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Molina

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[54] **IMPLANTABLE DEFIBRILLATOR LEAD**

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[51] **Int. Cl.**[6] **A61N 1/05**

[52] **U.S. Cl.** **607/129**; 600/374

[58] **Field of Search** 607/122, 129–132; 600/373–375

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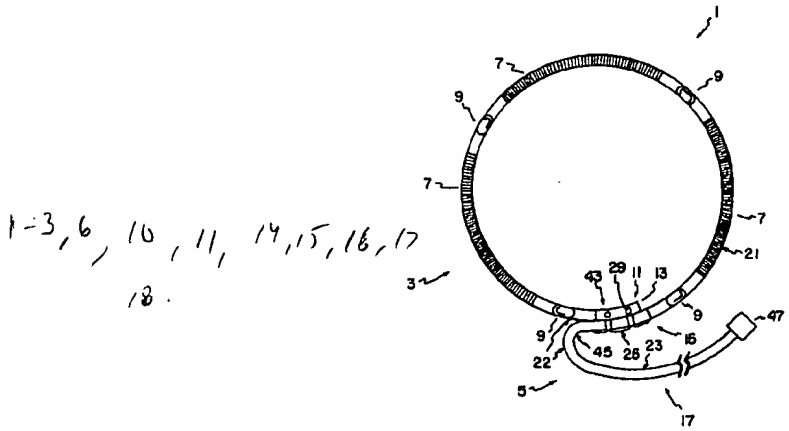
[57] **ABSTRACT**

The invention includes an implantable epicardial defibrillator lead with a linear assembly of sensors and coils that is formed into a loop upon implanting in a patient and a method for implanting this lead on a diaphragmatic surface of the pericardium.

19 Claims, 5 Drawing Sheets



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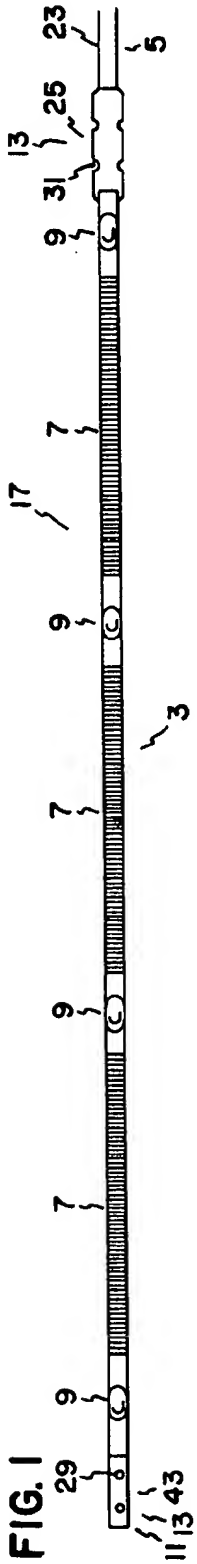


FIG. 1

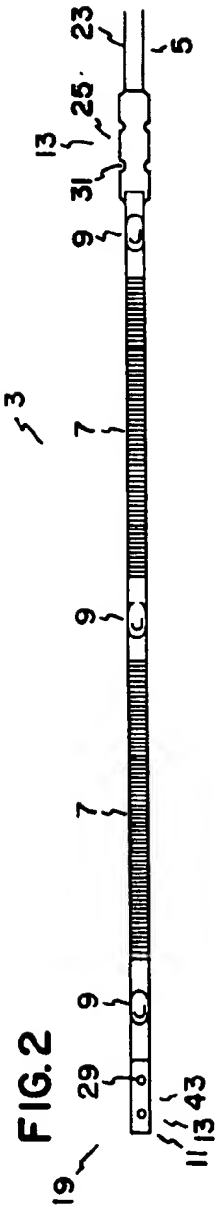


FIG. 2

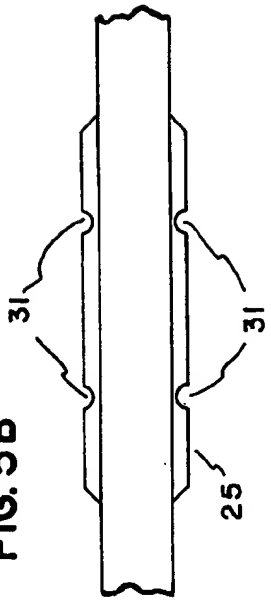


FIG. 5B

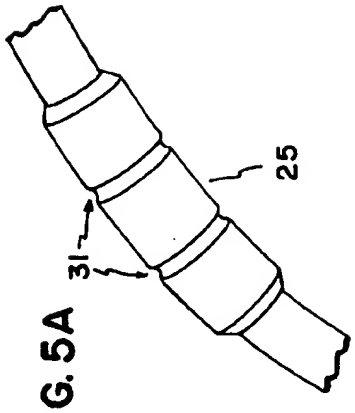


FIG. 5A

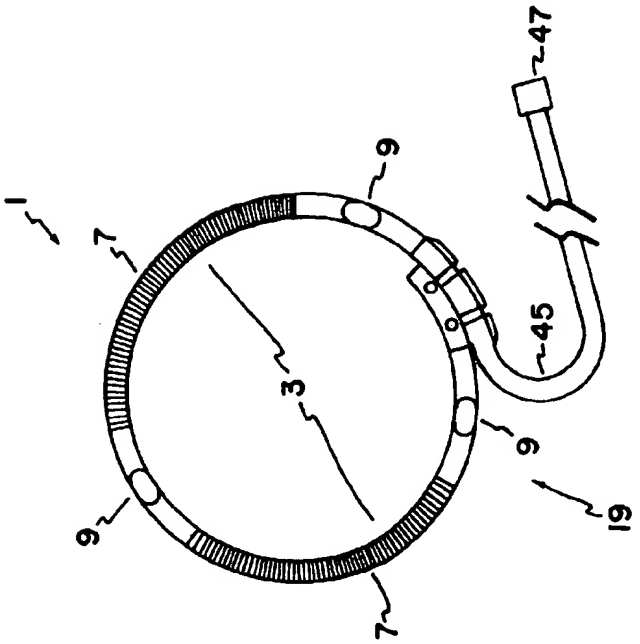


FIG. 4

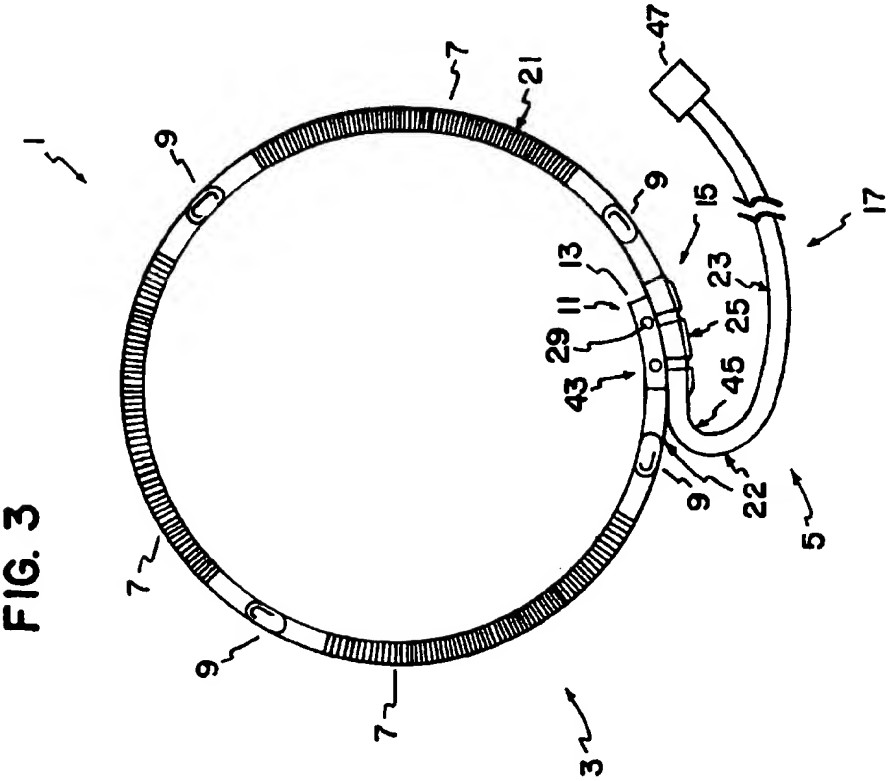


FIG. 3

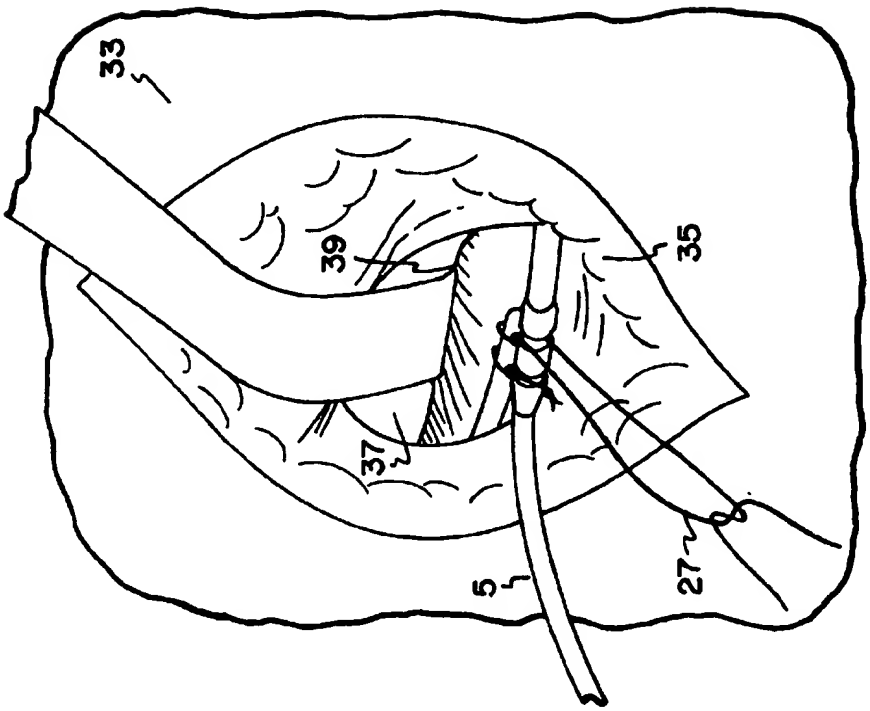


FIG. 8

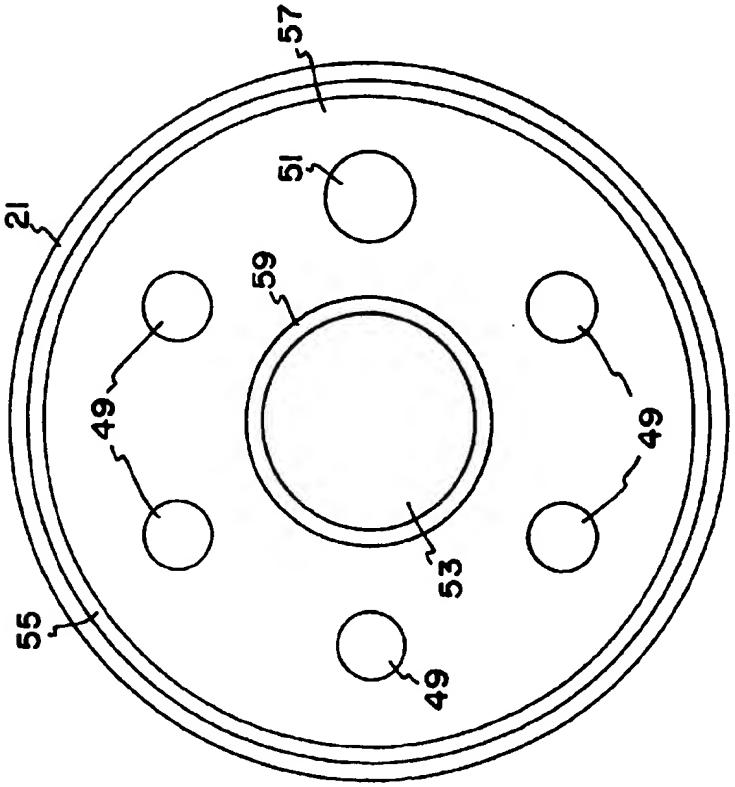


FIG. 6

FIG. 7A

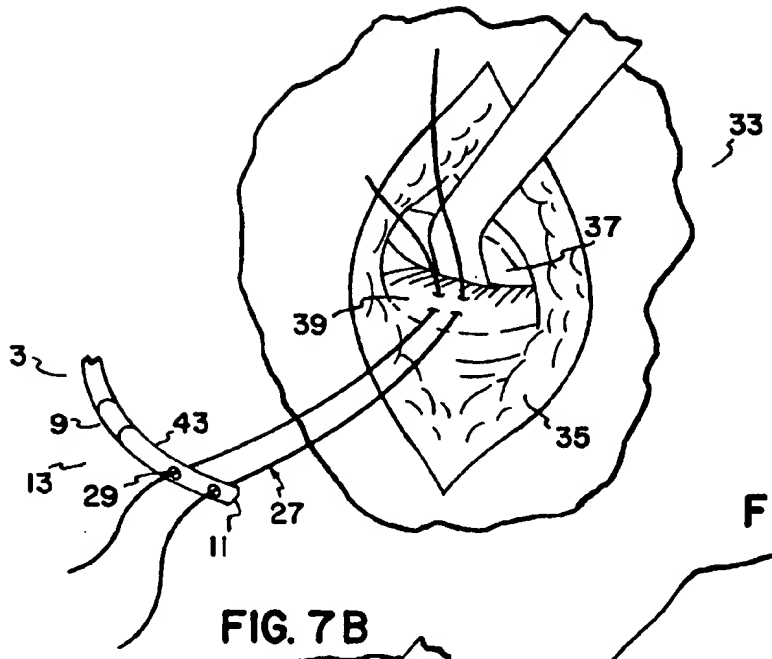


FIG. 7C

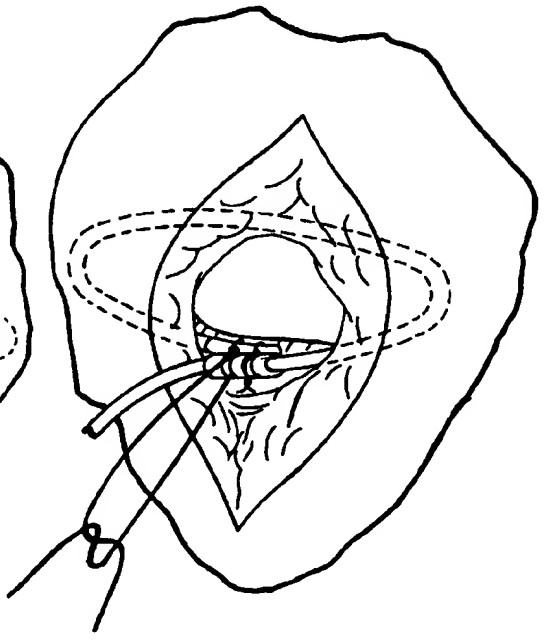


FIG. 7B

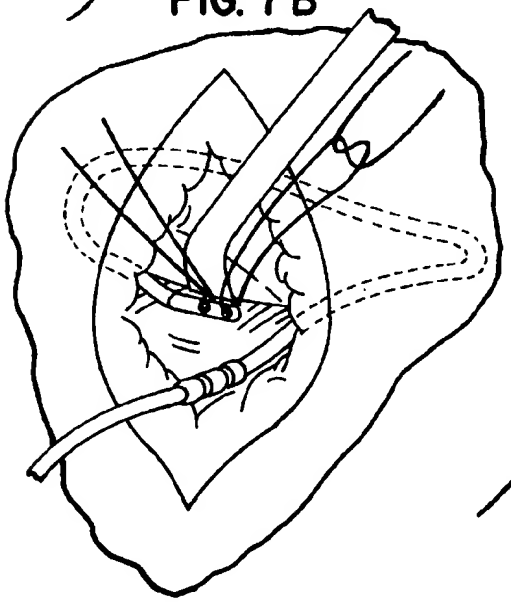
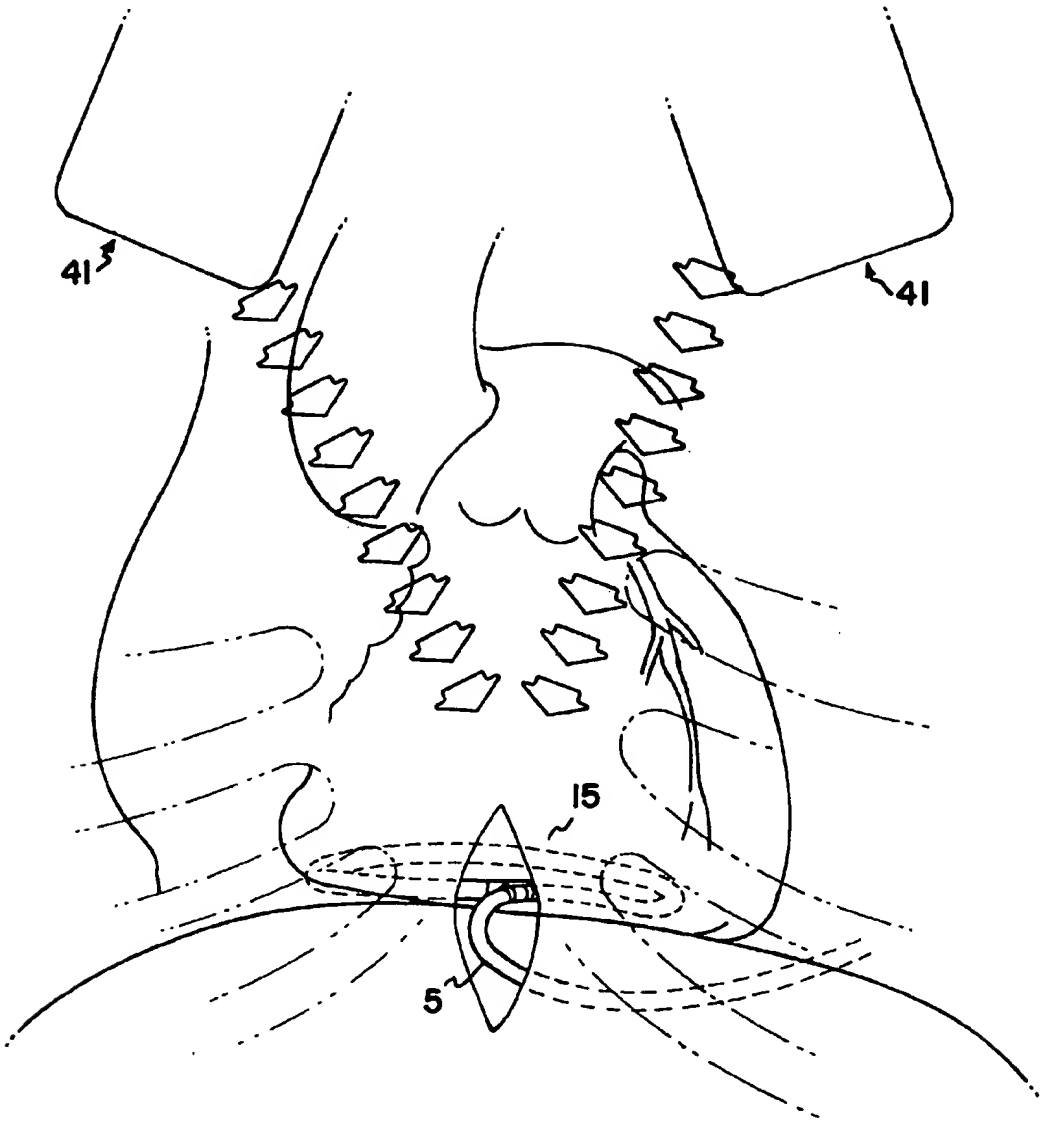


FIG. 9



IMPLANTABLE DEFIBRILLATOR LEAD

BACKGROUND OF THE INVENTION

Implantable cardiac defibrillators include patch defibrillators with a lead configured as a patch, which is attached to the surface of the heart or embedded in the patient subcutaneously. For example, one early patch lead included a rectangular patch that is applied around the patient's heart and is implanted by performing a thoracotomy on the patient. Other modifications or additions to the early patch designs were aimed at improved performance, improved patient tolerability, and simplified implanting. Despite improvements, patch leads typically suffer from a significant degree of crinkling, migration, erosion, and other problems related to the patch. Another drawback to patch leads is the need for surgery to implant the patch lead. This results in significant levels of operative mortality and infection of the patch, which can cause a life-threatening condition. Patch leads are undesirable because of these structural problems and risk of fatal complications.

Transvenous implanting of defibrillator leads was developed as an alternative to patch defibrillators. A transvenous lead including a defibrillator coil is typically inserted via the subclavian, internal jugular, or cephalic veins. Compared to the patch defibrillator leads, the transvenous leads show a reduction of operative mortality and are easier to implant. However, many transvenous systems require several coils in the right ventricle, the superior vena cava, the innominate vein, and sometimes even in the coronary sinus. This requires numerous leads all going in the same vein. This is undesirable because of consequences such as fibrosis or occlusion of the subclavian vein, obliteration of the superior vena cava, or simply mechanical obstruction of the vein. In addition, some of the transvenous systems require placement of a patch on the chest wall to render them effective. Using a patch results in all of the potential problems of patch leads and removes many of the advantages of the transvenous lead.

Although using transvenous leads reduced mortality and the number of complications, compared to patch leads, significant problems still occurred. One major problem is that transvenous leads migrate within the patient. Removal of a transvenous lead can also be a severe problem. Some of patients receiving transvenous leads are transplant candidates who receive a transvenous defibrillator system as a temporary measure, while awaiting transplant, to prevent sudden death from arrhythmia. In this case removal may not be a problem if the lead is removed soon after implantation. However, most of the transvenous leads having been in place for several weeks or months are extremely difficult to remove to allow the implant of the donor heart.

Because an intravenous lead that has been implanted for a long time is extremely difficult to remove, they can create problems if they fail. For example, there may not be room in the vein for additional leads. Overall, removing a transvenous lead requires a risky and difficult operative procedure. Frequently, removal requires cardiopulmonary bypass.

Transvenous defibrillator leads also cause other significant complications. For example, a transvenous lead can result in thrombosis of the subclavian or innominate veins, a complication which is usually irreversible. Severe fibrosis of the leads on the endocardial surface of the heart also occurs. This increases the defibrillation thresholds and makes removal of the leads impossible. Other complications include dislodgement, right ventricular perforation, creation of ventricular septal defect, infection, right atrial thrombus

formation, subclavian vein thrombosis, pulmonary embolism, insulation breakage, development of a crush or compression fracture of the leads, and embolization of the distal lead.

Problems related to the use of transvenous leads increase health care costs. Complications of transvenous leads result in hospital readmissions, operative lead revisions, lead replacement, and lead failures. The so-called lead crush syndrome, which is the pinching of the transvenous leads at the thoracic inlet between the clavicle and the first rib is a very well known problem, not only with defibrillators, but pacemaker systems as well. The problem of chronic subclavian vein obstruction is not a mild one and some of those patients cannot be treated, even surgically, to reestablish the patency of the vessels.

Many patients are not candidates for receiving a transvenous defibrillator. For example, patients who have had either previous transvenous systems and have developed fibrosis and/or occlusion of the subclavian vein are not candidates for further transvenous leads. Some patients develop obliteration of the superior vena cava due to multiple leads previously placed. Some patients with transvenous pacemakers of the bipolar type, which include two leads in addition to the lead used for the defibrillator, do not have room for additional leads. The innominate, subclavian, and superior vena cava veins do not have limitless capacity to take so much hardware. Other patients, such as children, simply are not candidates for transvenous defibrillator systems. Although not a large population, there are children who require defibrillator therapy and are unable to receive it because of a lack of a proper device, either of the transvenous or patch designs.

To overcome these limitations and avoid these problems, a new simple epicardial implantable defibrillator lead was developed.

SUMMARY OF THE INVENTION

The present invention relates to a defibrillator lead, and a method of implanting the lead that meet the needs described above. The defibrillator lead of the invention includes an system of one or more coils and one or more sensors in a linear arrangement and which can be configured as a loop. The lead also includes a conductor system for coupling the loop system to a pulse generator. The lead can be configured for use in an adult or a child. Compared to a pediatric lead, an adult lead has one or more additional coils, one or more additional sensors, a larger diameter loop, or a longer connector system. In one preferred embodiment, the lead is configured for connection to and used for defibrillating with standard pulse generators and pulsing protocols.

The lead can be implanted in a patient by a method that does not require opening either the chest or the heart. The lead can be introduced into the pericardium through a transxiphoid or subxiphoid incision and secured to the diaphragmatic surface of the pericardium. In a preferred embodiment, the lead is fastened in a looped configuration and secured to the pericardium with a single suture. The lead can be configured and implanted to be removable.

BRIEF DESCRIPTION OF THE DRAWINGS

Brief Description of the Drawings

FIG. 1 shows a configuration of the epicardial implantable defibrillator lead suitable for implanting in an adult. The loop system is in a linear arrangement which can be implanted in an adult patient and formed into a loop during implanting. The connector system is truncated in the Figure.

FIG. 2 shows a configuration of the epicardial implantable defibrillator lead suitable for implanting in a child, a pediatric lead. The loop system is in a linear arrangement which can be implanted in a pediatric patient and formed into a loop during implanting. The connector system is truncated in the Figure.

FIG. 3 shows a configuration of the adult epicardial implantable defibrillator lead with the loop system formed into a loop and showing the ends of the connector system. This lead corresponds to the adult lead shown in FIG. 1.

FIG. 4 shows a configuration of the pediatric epicardial implantable defibrillator lead with the loop system formed into a loop and showing the ends of the connector system. This lead corresponds to the pediatric lead shown in FIG. 2.

FIG. 5 shows a sleeve portion from one embodiment of a closure segment.

FIG. 6 shows a cross sectional view of an embodiment of the loop system including a conductive portion of a coil, several conductor members, a memory member, and a stylet.

FIGS. 7A, 7B and 7C show a schematic presentation of the process of implanting the epicardial implantable defibrillator lead.

FIG. 8 illustrates a single point of attachment for the loop portion of the lead.

FIG. 9 is a schematic illustration of the direction of the vectors of electrical energy traveling between the pulse generator and the epicardial implantable defibrillator lead.

DETAILED DESCRIPTION OF THE INVENTION

The Epicardial Implantable Defibrillator Lead

The lead of the invention is now discussed with reference to particular embodiments shown in FIGS. 1–9.

The epicardial implantable defibrillator lead of the invention includes a loop system with a linear array of one or more coils and one or more sensors, which can be arranged as a loop. The lead of the invention also includes a connector system adapted and configured to couple the loop system to a pulse generator. The connector system includes a conductor within an insulating sheath or cover.

Within the loop system, one or more coils and one or more sensors are arranged in a linear array. The linear array provides for ease of implanting the lead in a patient, facilitates removal from the patient, and an advantageous arrangement of one or more coils and one or more sensors. One advantageous aspect of this arrangement of coils and sensors is that only a single component need be implanted in a patient to provide both sensors and coils. Another advantageous aspect of this linear array of sensors and coils is that the spatial relationship of the coils and sensors in the linear array provides a predetermined arrangement of coils and sensors when the lead is inserted into a patient and formed into a loop.

A coil includes a conductive portion that is typically a coiled conductor and can form all or part of the coil. The coil is adapted and configured to couple to a sensor. By coupled it is meant that a coil and sensor are physically joined by any number of ways understood by those practicing the invention including physically connected, fused, cemented, welded, or the like. Sensor and coil are electrically isolated or insulated from one another. One or more coils and one or more sensors can also be formed as a one piece arrangement. One sensor to be employed in the lead of the invention is the type used in defibrillators or pacers for sensing heart rhythm and providing data regarding the rhythm to a pulse generator. The lead of the invention also includes a closure segment adapted and configured to form a loop from the arrangement of sensors and coils within the insulating sheath. The lead of the invention can also include an attachment system adapted and configured for attaching the lead to a patient.

The lead of the invention can be adapted and configured for implanting in an adult or a child. Adults are larger than children, and they typically require a larger loop so that the pulse goes through the entire heart and a longer connector system capable of reaching the pulse generator. Reflecting this difference in size, a pediatric lead of the invention typically includes two coils and three sensors and an adult lead typically includes three coils and four sensors.

FIGS. 1–4 show preferred embodiments of lead **1**. As described later herein FIGS. **1** and **3** show an adult lead **17** and FIGS. **2** and **4** show a pediatric lead **19**. Each lead **1** shown in FIGS. 1–4 has a loop system **3** and a connector system **5**. As shown, loop system **3** has a linear arrangement of coils **7** and sensors **9** that can be formed into a loop. In these Figures, loop system **3** has alternating sensors **9** and coils **7**, with the loop **15** beginning and ending with a sensor **9**. Each sensor **9** is coupled, but not electrically connected, to at least one coil **7**, and each coil **7** is coupled to two sensors **9**. Coils and sensors are coupled using standard connectors used for coupling components of defibrillators and which insulate sensor **9** from coil **7** as they connect to the pulse generator. Internally, as shown in FIG. **6**, loop system **3** can include one or more insulated conductive members **49**, each of which connect one or more individual sensors **9** or one or more individual coils **7** to connector system **5**. Another internal component of loop system **3** can be biasing or memory member **51**, which provides biasing force that urges loop system **3** to form loop **15** within a body. Loop system **3** an be generally tubular and define lumen **59** that provides access for inserting stylet **53**. Stylet **53** aids in insertion of loop system **3** into a patient, and can provide additional stiffness as loop **15** is formed in the patient.

Connector system **5** connects loop system **3** to a pulse generator **41**. As shown in FIGS. **3** and **4**, connector system **5** has ends **47** and **45** for coupling to pulse generator **41** and to loop system **3**, respectively. A standard connector can be used for coupling to pulse generator **41** and to loop system **3**.

To form a loop **15** from loop system **3** and to join loop system **3** to connector system **5**, a closure segment **13** is provided. As shown in FIGS. **3** and **4**, ends of loop system **3** are joined by closure segment **13** to form loop **15**. Closure segment **13** includes sleeve **25** (shown in FIGS. 1–5) and perforation member **43** (shown in FIGS. 1–4), which are adapted and configured for closing the loop with a suture. Preferably, perforation member **13** has perforations **29** through which suture **27** can be threaded. Preferably, sleeve **25** has in its surface grooves **31**, which are configured to restrain suture **27**. The length of loop system **3** between perforation member **13** and sleeve **25** is the circumference of loop **15**. Other closure systems for closing the loop and forming the loop/connector lead can be employed, such as using additional sutures or stitches as desired to obtain stability of the lead relative to the pericardial surface.

Generally, loop **15** can be formed in any of a variety of ways. Loop system **3** can be formed into a loop **15**, for example, by attaching an end **11** of loop system **3** to a portion of either loop system **3**, connector system **5**, or closure segment **13**. Alternatively, a portion of loop system **3** can be attached to a distal portion of loop portion **3**, or to connector system **5**, or closure segment **13**. In another embodiment, loop **15** can be formed using closure segment **13**, which can employ any of a variety of mechanisms for forming a loop **15** from loop system **3**. For example, loop **15** can be closed by an apparatus or system that snappably

engages, welds, adheres, or otherwise fastens a portion of loop system **3**, preferably end **11**, to loop system **3**, closure segment **13**, or connector system **5**.

In FIGS. **1–4**, each coil **7** is coupled to two sensors **9**, and each sensor **9** is coupled to one or more coils **7**. Generally, each coil **7** can couple either to another coil **7** or a sensor **9**, and each sensor **9** can couple to another sensor **9** or coil **7**. Thus, the lead of the invention can be configured in a variety of arrangements. In addition, a sensor **9** or a coil **7** can be configured to couple with, or can include components of closure segment **13**. For example, a coil **7** or sensor **9** can include features analogous to grooves **31** of sleeve **25** or to perforations **29** of perforation member **43**.

As shown in FIGS. **1–4**, coil **7** is made from materials and in configurations known in the art for high current, low resistance defibrillator coils. In FIGS. **1–4** entire coil **7** is shown as a conductor, although one of skill in the art will appreciate that only a portion of coil **7** need be of conductive material or a discrete conductor element can be included as a portion of the coil. For example, coil **7** can be a single or multifilar coil, a tinsel wire coil, a braided coil, or the like. Typically, coil **7** is made from a material such as MPN30, Eljalloy, nitinol wire, titanium wire coated with platinum, a nickel-titanium alloy, platinum-iridium, a similar metal conductor, or the like. Typically, the conductive portion **21** of coil **7** is shaped as a generally tubular coil, helix or spiral, is exposed over all of or a majority of the length of coil **7**, and is insulated from any sensor **9**. Typically, each coil **7** is spatially isolated from and is insulated from any other coil **7**. The generally tubular conductive portion **21** of coil **7** can include in its lumen **55** a conductor member **49** enclosed within an insulator **57** (as shown in FIG. **6**), for purposes such as connecting connector system **5** to sensor **9** or to another coil **7**. Lumen **55** can also house memory member **51**, stylet **53**, or the like (FIG. **6**).

A sensor **9**, shown in FIGS. **1–4**, can be made from materials and in configurations known in the art for sensors for defibrillators or pacers. For example, sensor **9** can be a sense electrode, a surface electrode for sensing and pacing with or without steroid eluting construction, or the like. Sensor **9** is typically of the same diameter of loop system **3** and coil **7**, or slightly prominent. If sensor **9** is prominent it will typically be tapered at both ends to facilitate removal of the lead from the patient, if this becomes necessary. Typically, a sensor **9** can detect a cardiac rhythm and pace the ventricles without penetrating the epicardium. Sensor **9** can be coupled to pulse generator **41** either individually, so that pulse generator **41** can receive a signal from sensor **9** alone, or jointly with one or more additional sensors **9**. Typically, each sensor **9** is connected individually to an insulated conductor member **49** that extends to connector system **5**. Sensor **9** can include in its lumen **55** a conductor member **49** enclosed within an insulator **57** (as shown in FIG. **6**), for purposes such as connecting connector system **5** to another sensor **9** or to coil **7**. Lumen **55** can also house memory member **51**, stylet **53**, or the like (FIG. **6**). The lead can also be provided with one sensor or pacer implanted in the myocardium.

As shown in FIGS. **3** and **4**, connector system **5** is enclosed in insulating sheath **23**. Connector system **5** can be made from materials and in configurations known in the art for connecting a high current, low resistance defibrillator lead to a pulse generator **41**. Typical connector system configurations for connecting to a pulse generator are known as universal pin connectors. Typically, connector system **5** includes a conductor made from a material such as MPN30, Elj alloy, a similar metal material, a low resistance composite material, such as drawn braised stranded or drawn filled tubes, or the like. Connector system **5** is typically configured as an elongated conductor that can be enclosed in a tubular insulating cover **23**, and coupled to loop system **3** and pulse generator **41**.

Insulating sheath or cover **23** is typically a generally tubular sheath that encloses generally tubular connector system **5**. Second insulating sheath **23**, like other insulating materials used in the lead of the invention, is made of a material suitable for insulating electrical components from the human body and for implanting in the human body, such as silastic or another silicone containing rubber or polymer material. However, insulating sheath **23** can be of a material or in a configuration suitable for enclosing connector system **5**.

Lead **1**, loop system **3**, and connector system **5** can be configured to form an adult lead **17** or a pediatric lead **19**, as shown in exemplary embodiments in FIGS. **1–4**. An adult lead **17**, compared to a pediatric lead **19**, typically is longer and includes more coils **7** and sensors **9**. The adult body and heart are typically larger than a child's, which can require a larger lead **1**.

Adult Epicardial Implantable Defibrillator Lead

A typical adult lead **17**, shown in FIGS. **1** and **3**, includes three coils **7**, four sensors **9**, and a connector system **5** constructed to connect to a pulse generator **41** implanted above the heart in an adult chest. A preferred adult lead **17** includes a plurality of sensors **9**, typically about two to about six sensors **9**, preferably about four sensors **9** (FIGS. **1** and **3**), that act as a sensing point to detect cardiac function and also for pacing of the heart, if needed. Typically, each sensor **9** is about 1–3 cm in length, preferably about 2 cm. A preferred adult lead **17** includes a one or more coils **7**, typically about one to about five coils **7**, preferably about three coils **7** (FIGS. **1** and **3**), that provide defibrillation current. Typically, each coil **7** is about 4–6 cm in length, preferably about 5 cm. As shown in FIGS. **1** and **3**, the coils and sensors of an adult epicardial defibrillator lead of the invention are generally cylindrical or tubular in shape with an outside diameter of about 2–4 mm, preferably about 3 mm.

A typical adult lead **17** shown in FIGS. **1** and **3** measures, from end **47** of connector system **5**, which connects to a pulse generator **41**, to end **11** of loop system **3**, about 55–70 cm, preferably about 62.5 cm. In such an adult lead **17**, loop system **3** is typically about 20–25 cm long, preferably about 22.5 cm, which forms a loop preferably about 7.5 cm in diameter. Connector system **5** of adult lead **17** is typically about 30–50 cm long, preferably about 40 cm. The length is chosen to allow sufficient distance to connect to pulse generator **41**, which is advantageously placed in the upper chest at the subclavicular area.

Pediatric Epicardial Implantable Defibrillator Lead

A typical pediatric lead **19**, shown in FIGS. **2** and **4**, includes two coils **7**, three sensors **9**, and a connector system **5** constructed to connect to a pulse generator **41** implanted above the heart in a child's chest. A preferred pediatric lead **19** includes a plurality of sensors **9**, typically about one to about five sensors **9**, preferably about three sensors **9** (FIGS. **2** and **4**), that act as a sensing point to detect cardiac function and also for pacing of the heart, if needed. Typically, each sensor **9** is about 1–3 cm in length, preferably about 2 cm. A preferred pediatric lead **19** includes one or more coils **7**, typically about one to about three coils **7**, preferably about two coils **7** (FIGS. **2** and **4**), that provide defibrillation current. Typically, each coil **7** is about 4–6 cm in length, preferably about 5 cm. As shown in FIGS. **2** and **4**, the coils and sensors of a pediatric epicardial defibrillator lead of the invention are generally cylindrical or tubular in shape with an outside diameter of about 2–4 mm, preferably about 3 mm.

A typical pediatric lead **19** shown in FIGS. **2** and **4** measures, from end **47** of connector system **5**, which connects to a pulse generator **41**, to end **11** of loop system **3**, about 25–55 cm, preferably about 40 cm. In such an pediatric lead **19**, loop system **3** is typically about 10–20 cm

long, preferably about 15 cm, which forms a loop preferably about 5 cm in diameter. Connector system **5** of pediatric lead **19** is typically about 15–35 cm long, preferably about 25 cm. The length is chosen to allow sufficient distance to connect to pulse generator **41**, which is advantageously placed in the upper chest at the subclavicular area.

Implanting the Epicardial Implantable Defibrillator Lead

The lead of the invention is advantageously positioned as a loop between the inferior surface of the heart and the dome of the diaphragm. The loop can be created by tying or stitching together a tip of the lead to an axis behind the last coil. The loop includes the active end of the lead coiled upon itself as a loop. One configuration of the lead allows the linear lead to be introduced through a small subxiphoid incision, the loop being formed during introduction, the loop structure being closed by a suture that also fastens the lead to the patient.

Implanting the lead of the invention is illustrated schematically in FIGS. **7A**, **7B** and **7C**. Lead **1** can be implanted in patient **33** by a method including making a transxiphoid or subxiphoid incision **35** in patient **33**. Using such a simple approach, lead **1** typically is implanted without use of fluoroscopy, but is done under direct vision in the operating room. Incision **35** allows access to pericardium **37** and to a diaphragmatic surface **39** of pericardium **37**. Lead **1** can be inserted into pericardium **37** through incision **35**. Such an incision **35** opens pericardium **37** and only a small incision **35** opening on a small space is needed to place stitches **27** on diaphragmatic surface **39** of pericardium **37**.

Advantageously, lead **1** is secured to diaphragmatic surface **39** of pericardium **37**, for example using sutures **27** and end **11**, before advancing the remainder of lead **1** into pericardium **37**. When an appropriate amount of lead **1** has been advanced into pericardium **37** loop **15** can be closed, for example with suture **27**, end **11**, and sleeve **25**. Perforation member **43** at end **11** of loop system **3** can include a perforation **29**, preferably two perforations **29**, through which one or more stitches **27** can be placed. Stitch **27** is used to anchor end **11** to the dome of the diaphragm **39** at the xiphoid level and to close loop **15**. Alternatively, loop **15** can be closed prior to advancing lead **1** or loop system **3** into pericardium **37**. Before or after the loop is secured, stylet **53** can be removed from loop system **3**. Once secured, loop **15** advantageously has a horizontal position over the diaphragmatic surface of the pericardium (as shown in FIGS. **7A**, **7B**, **7C** and **9**) and lays over the dome of diaphragm **39** between diaphragm **39** and the inferior surface of the heart. Advantageously, lead **1** is anchored to diaphragm **39** only at the point where tip **11** and sleeve **25** are tied together.

After lead **1** is secured to diaphragmatic surface **39** of pericardium **37** of subject **33**, incision **35** can be closed and connector system **5** can be coupled to pulse generator **41**. For connection to pulse generator **41**, connector system **5** is tunneled up to the subclavicular area where pulse generator **41** is implanted, usually on the left side of patient **33**, but the right side can be used as well. Advantageously, lead **1** lays horizontally covering the entire inferior surface of the heart and pulse generator **41** can be located on the left or right of the upper chest. Preferably pulse generator **41** is positioned in the subclavicular area, preferably retropectorally.

Because the entire ventricular septum in the human has a generally horizontal orientation where the right ventricle lies on top behind the sternum and the left ventricle is posterior to it and towards the left, any electrical shock coming from the upper part of the body (subclavicular right or left) to reach loop lead **1** will typically have a vector generally shaped like a cone or a pyramid and the current will have to go through the entire thickness of the ventricle including the septum. Vectors of current obtained using the lead of the invention are shown schematically in FIGS. **7A**, **7B** and **7C**. The area covered by the lead of the invention, therefore, will be substantially more than a single straight lead placed inside the right ventricular chamber as it occurs with a transvenous lead system. No additional intravenous lead or patch lead is required to supplement the loop lead of the invention. Advantageously, in a lead with multiple sensors, at least one sensor maintains contact with the heart at all times.

Testing involved with this lead is advantageously reduced compared to conventional intravenous leads or patch leads, since the lead of the invention is one lead placed in the pericardium. Advantageously, even in patients who have undergone previous cardiac surgery, there won't be any need to reopen the entire chest. Through the subxiphoid approach, the inferior surface of the heart could be dissected to a significant distance to position a lead of the invention. In cardiac surgery patients who have had previous interventions, the only surface that remains relatively free of adhesions or easy to enter is the inferior surface of the heart which is the space between this and the dome of the diaphragm, which is the area where the lead of the invention is implanted. This type of lead can also be implanted in children through a small incision in the subxiphoid area.

Method of Treatment Using the Epicardial Implantable Defibrillator Lead

The lead of the invention can be used to treat disorders requiring defibrillation by a method including determining that a patient needs defibrillation, implanting a defibrillator lead of the invention, sensing an arrhythmia, and activating the defibrillator lead to provide defibrillation. Another method for treating arrhythmia in a patient in which the lead has already been implanted includes sensing an arrhythmia and activating the defibrillator lead to provide defibrillation. The lead of the invention can be activated by pulse generator systems known in the art.

The disorder requiring defibrillation can be diagnosed and detected by methods known in the art. Disorders requiring defibrillation include an arrhythmia arising from alteration in impulse generation leading to enhanced or abnormal automaticity, or from an abnormality in impulse conduction, which can result in the reentry phenomenon; an atrial arrhythmia such as atrial flutter or fibrillation, and paroxysmal supraventricular tachycardia; a ventricular arrhythmia such as acute ventricular tachycardia, or a refractory ventricular arrhythmia or tachycardia; a supraventricular arrhythmia or ectopic arrhythmia; an arrhythmia arising during or associated with myocardial ischemia or myocardial infarction; and an arrhythmia leading to sudden arrhythmic death.

Removing the Epicardial Implantable Defibrillator Lead

Advantageously, if the lead is no longer needed or if complications arise, the lead can be removed by cutting the stitch holding it to the pericardium and sliding the lead out, for example, by pulling on the connector system. This can be done under local anesthesia. Such simple removal is in contrast to the major dissection or surgical procedure involving exposure of the heart, which is required to remove an intravenous lead or an epicardial patch that has become infected or has eroded into the myocardium.

Indications for the Use of the Epicardial Implantable Defibrillator Lead

The epicardial implantable defibrillator lead of the invention can be the first-line approach for any patient who needs

a defibrillator. However there are numerous indications for which the lead of the invention is particularly advantageous. For example:

1. When a single transvenous lead placed in the right ventricle is not effective, or requires additional electrodes to function adequately, the lead of the invention is advantageous compared to implanting additional electrodes to compensate for ineffectiveness of the single transvenous lead.
2. When a transvenous system fails, or is no longer effective, it can be replaced by a lead of the invention.
3. The lead of the invention is advantageous for all candidates for heart transplant who have a need for an implanted defibrillator lead while awaiting transplantation. Transvenous leads cause serious problems in a heart that is to be excised.
4. When a transvenous lead system cannot be implanted due to upper vein occlusions, the lead of the invention can be implanted.
5. In children or small patients who cannot accept transvenous leads due to the small size of their veins.

The present invention may be better understood with reference to the following example. The example is intended to be representative of specific embodiments of the invention, and are not intended as limiting the scope of the invention.

EXAMPLE

Leads of the invention have been implanted in lambs. Each lead implanted in a lamb had 2 coils, 1 sensor, a loop system 22 cm long, and a connector system 45 cm long. The lambs were tested for thresholds in the acute stage at 3 months and 9 months after implanting the lead of the invention. The lambs were also subjected to 2 periodic CT scans or chest X-rays to assess whether the lead had become either displaced or dislodged.

None of the leads were displaced or dislodged. In each of the lambs, cardiac electrical parameters remained satisfactory up to 9 months following the implant. After 10 months the lambs remain in good health and the lambs have been defibrillated after inducing ventricular fibrillation in every case.

The invention has been described with reference to various specific and preferred embodiments and techniques. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention resides in the claims hereinafter appended.

I claim:

1. An epicardial implantable defibrillator lead comprising:

a loop system having a first end and a second end, the loop system comprising a sensor, a coil, and a closure segment comprising a perforation member and a sleeve; the coil comprising a generally tubular conductive portion defining a lumen, the lumen comprising an insulator, the insulator enclosing a conductor member, a memory member, or both; the sensor, coil, perforation member and sleeve being coupled in linear arrangement with the perforation member located proximal to the first end and the sleeve located proximal to the second end; and

a connector system having a first end and a second end, the first end of the connector system coupled to the second end of the loop system, the second end adapted to be coupled to a pulse generator, the connector system comprising an insulating cover enclosing a conductor; the conductor passing through the connector system and connecting with either the coil or sensor.

2. The defibrillator lead of claim **1**, wherein the lead is a pediatric lead.

3. The defibrillator lead of claim **2**, wherein the loop system comprises three sensors and two coils, each coil being coupled to two sensors.

4. The defibrillator lead of claim **1**, wherein the lead is an adult lead.

5. The defibrillator lead of claim **4**, wherein the loop system comprises four sensors and three coils, each coil being coupled to two sensors.

6. The defibrillator lead of claim **1**, wherein the sensor detects cardiac rhythm and paces a ventricle without penetrating the epicardium.

7. The defibrillator lead of claim **1**, wherein the insulating cover comprises silicon or silastic.

8. The defibrillator lead of claim **1**, wherein the perforation member and the sleeve, when connected retain the loop system as a loop.

9. The defibrillator lead of claim **8**, wherein the perforation member comprises perforations therein for threading a suture therethrough and the lead further comprises a suture, wherein the suture threaded through the perforations is used to attach the lead to a patient.

10. A method for implanting an epicardial implantable defibrillator lead in a patient in need thereof, the method comprising the steps of:

making a transxiphoid or subxiphoid incision in the patient;

accessing the pericardium;

securing the lead to the diaphragmatic surface of the pericardium;

advancing the lead into the pericardium; and

closing the incision.

11. The method of claim **10**, the step of securing comprising:

stitching the lead to the diaphragmatic surface of the pericardium.

12. The method of claim **10**, the method further comprising the step of:

forming a loop in the lead.

13. The method of claim **12**, the step of forming comprising:

tying or stitching together two portions of the lead.

14. The method of claim **13**, wherein a single suture ties or stitches together the two portions of the lead and secures the lead to the diaphragmatic surface of the pericardium.

15. The method of claim **10**, wherein the step of advancing comprises:

positioning the lead in a region proximal to the apex of the heart, the AV groove, and the left and right borders of the heart.

16. The method of claim **10**, wherein the step of advancing comprises:

positioning the lead on the diaphragm in a region corresponding to the inferior surface of the heart in a generally horizontal plane.

17. The method of claim **10**, further comprising the step of:

implanting a pulse generator in the subclavicular area of the subject; and

connecting the pulse generator to the lead.

18. The method of claim **17**, wherein the pulse generator is implanted in the patient's left side.

19. The method of claim **17**, wherein the pulse generator is implanted in the patient's right side.

* * * * *

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United States Patent [19]

Dahl et al.

[11] Patent Number: 5,603,732

[45] Date of Patent: *Feb. 18, 1997

[54] **SUBCUTANEOUS DEFIBRILLATION ELECTRODES**

[75] Inventors: **Roger W. Dahl**, Andover; **David K. Swanson**; **Stephen J. Hahn**, both of Roseville; **Douglas J. Lang**, Arden Hills; **John E. Heil**, St. Paul, all of Minn.

[73] Assignee: **Cardiac Pacemakers, Inc.**, St. Paul, Minn.

[*] Notice: The portion of the term of this patent subsequent to Jun. 6, 2020, has been disclaimed.

[21] Appl. No.: **554,577**

[22] Filed: **Nov. 6, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 285,802, Aug. 4, 1994, Pat. No. 5,545,202, which is a continuation of Ser. No. 967,361, Jan. 4, 1993, Pat. No. 5,360,442, which is a continuation of Ser. No. 533,886, Jun. 6, 1990, Pat. No. 5,203,348.

[51] **Int. Cl.**[6] **A61N 1/05**

[52] **U.S. Cl.** **607/129**; 607/148; 607/152

[58] **Field of Search** 607/119, 129, 607/148, 152

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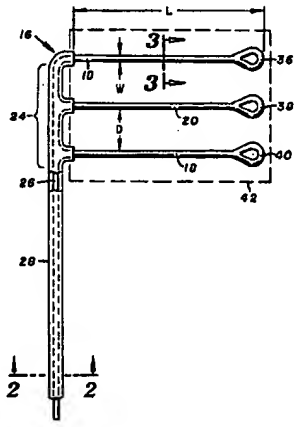
Primary Examiner—William E. Kamm
Assistant Examiner—Kennedy J. Schaetzle
Attorney, Agent, or Firm—Haugen and Nikolai, P.A.

[57] **ABSTRACT**

Implantable electrodes for defibrillation are formed of pluralities of electrode segments. Each of the segments is relatively long and narrow. The electrode segments can be parallel and spaced apart from one another a distance at least ten times the nominal width, with one end of each segment mounted to a transverse distal portion of an electrically conductive lead coupling the electrode to a defibrillation pulse generator. Alternatively, segments can branch or radiate outwardly from a common junction. In yet another arrangement, electrode segments are portions of a single conductive path at the distal end of a lead from a pulse generator, arranged in either a spiral configuration or a serpentine configuration which can align electrode segments side by side, parallel and spaced apart. The electrode segments can be formed of composite conductors in the form of titanium ribbons or wires with a sputtered outer layer of platinum, or a silver core in a stainless steel tube, with a platinum layer formed onto the tube. The electrodes are highly compliant yet can provide large effective areas for defibrillation, enabling a transthoracic pulsing arrangement of two electrodes on opposite sides of the heart, implanted subcutaneously outside of the thoracic region.

11 Claims, 5 Drawing Sheets



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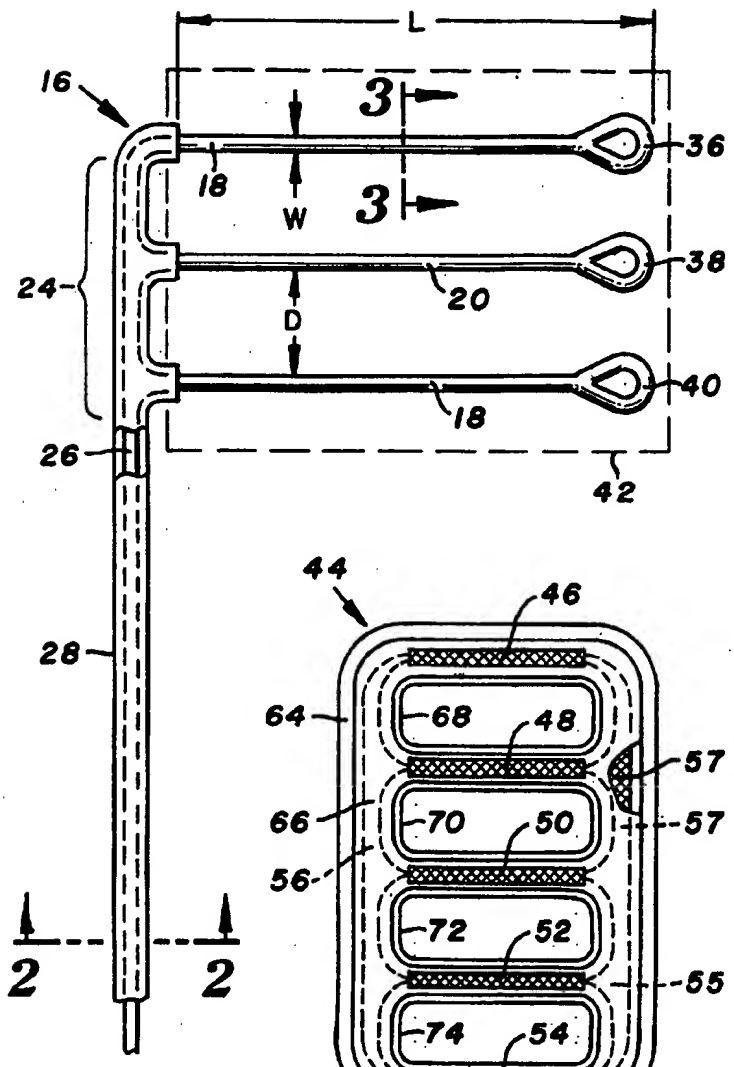

FIG. 1

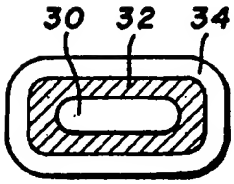

FIG. 2

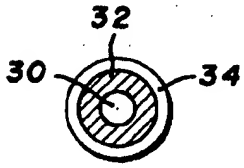

FIG. 3

FIG. 4

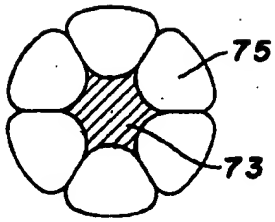

FIG. 5

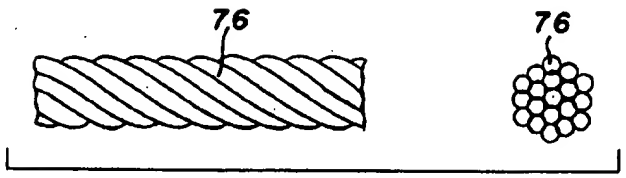

FIG.6

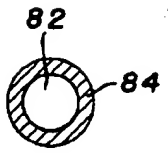

FIG.8

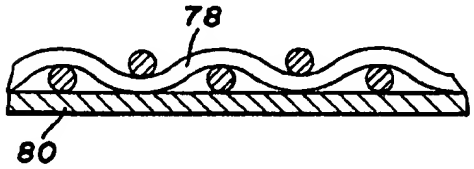

FIG.7

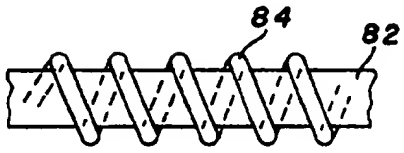

FIG.9

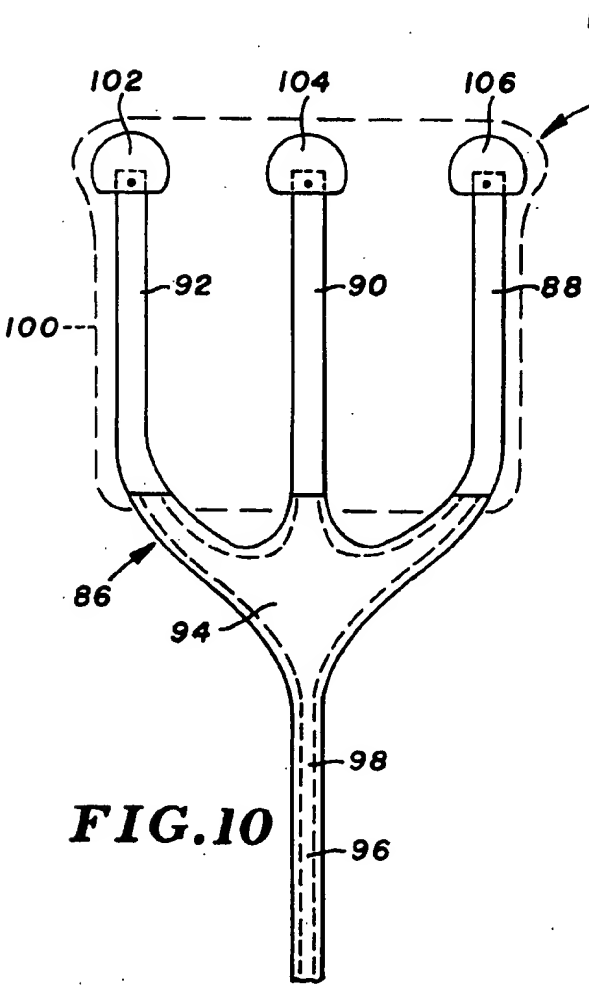

FIG.10

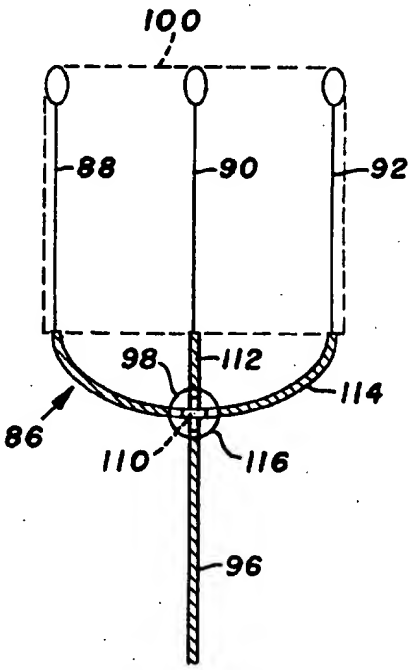

FIG.11

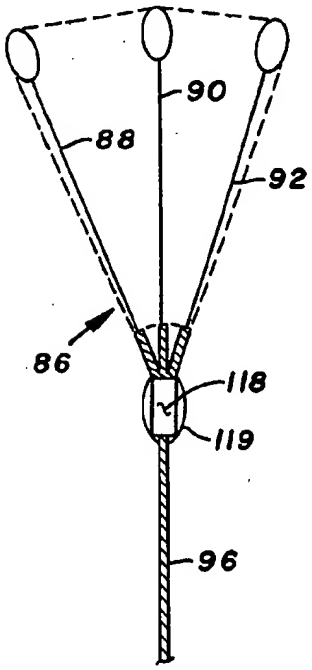

FIG. 12

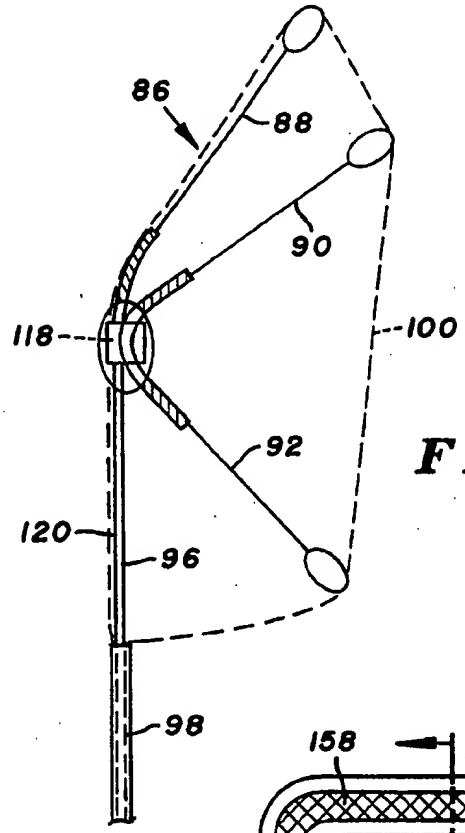

FIG. 13

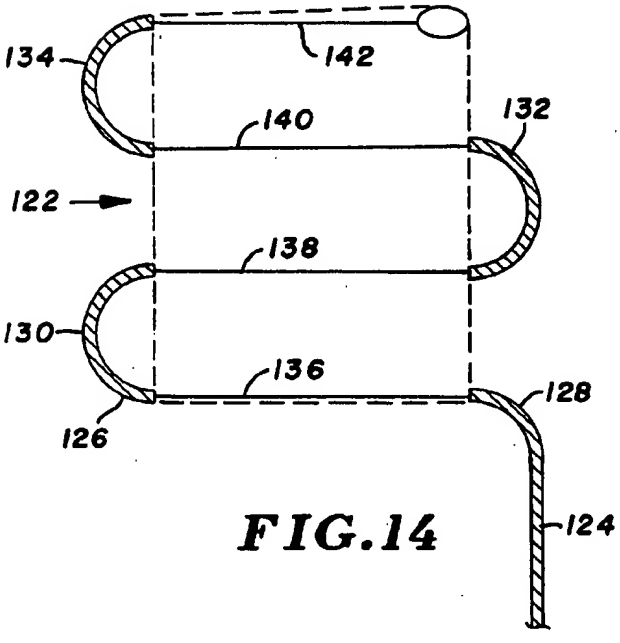

FIG. 14

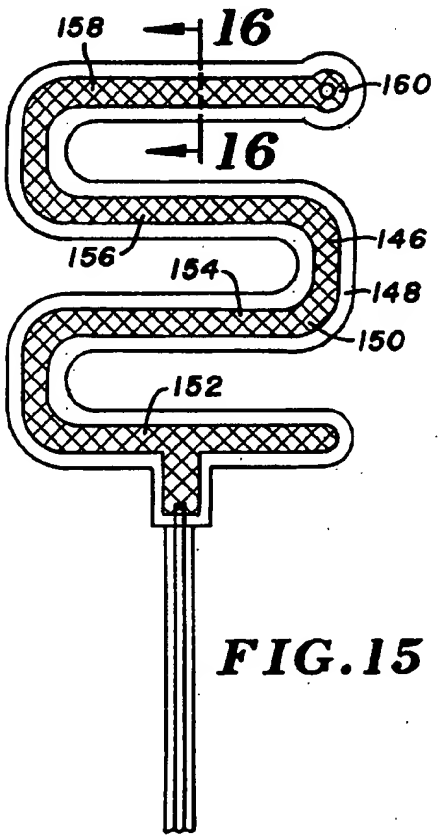

FIG. 15

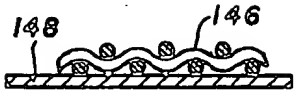

FIG.16

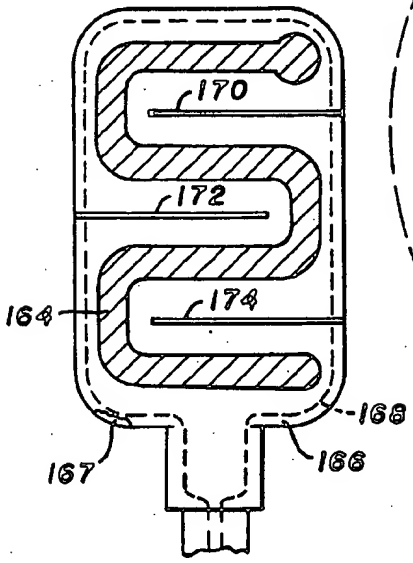

FIG.17

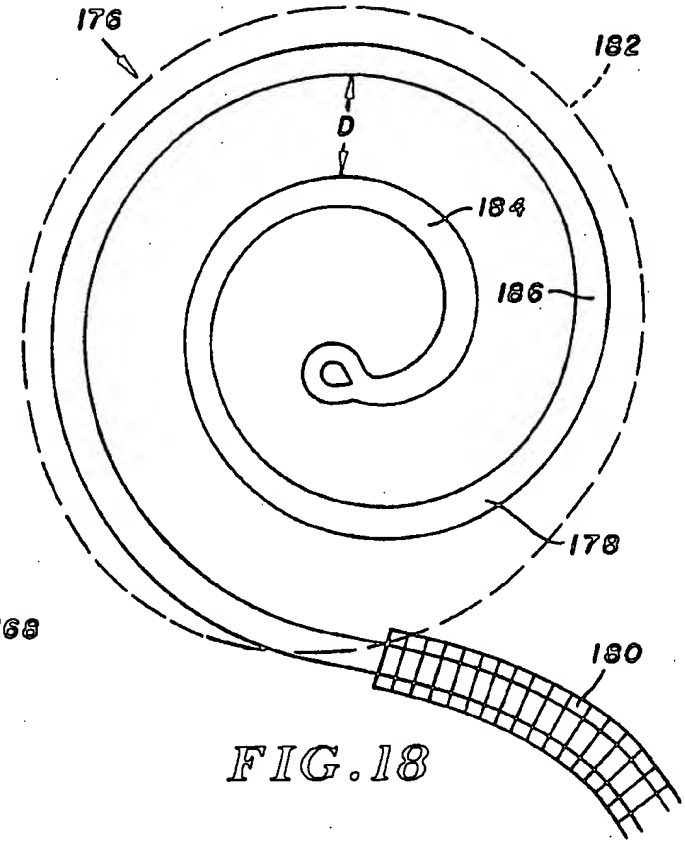

FIG.18

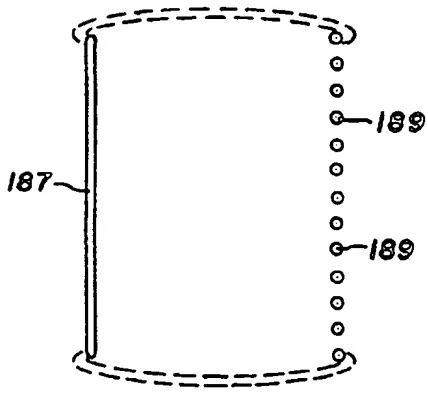

FIG.19

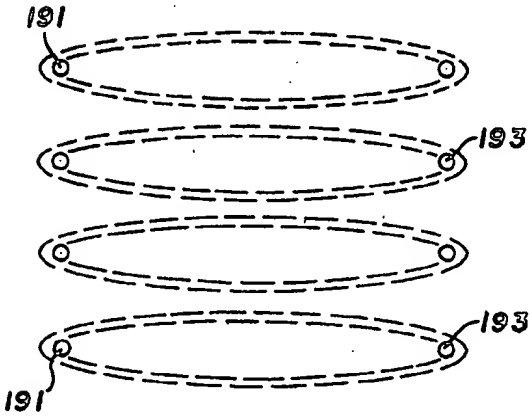

FIG.20

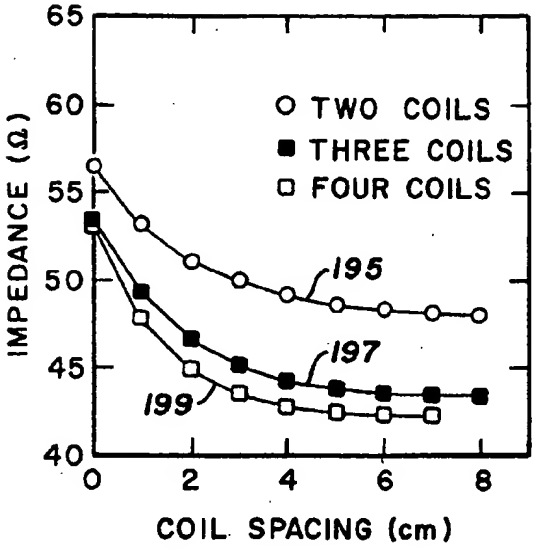

FIG. 21

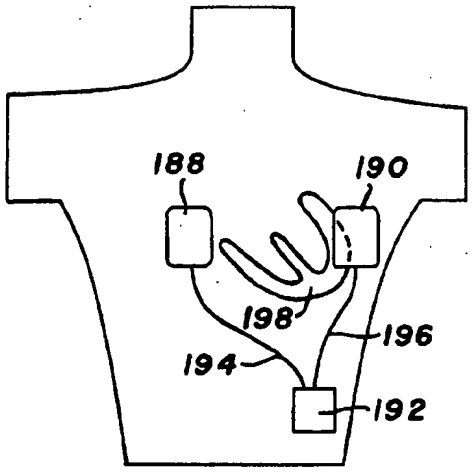

FIG. 22

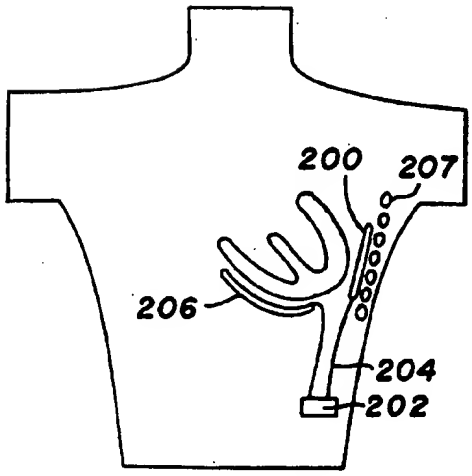

FIG. 23

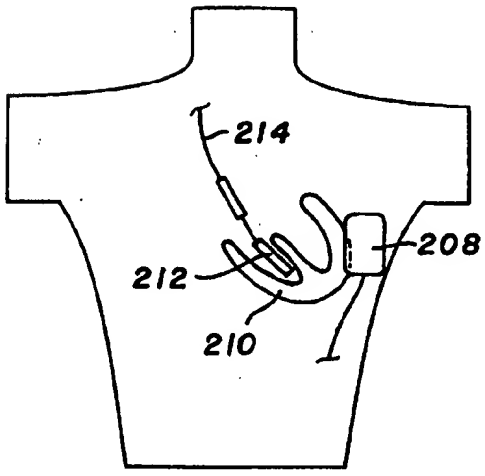

FIG. 24

SUBCUTANEOUS DEFIBRILLATION ELECTRODES

This is a continuation of application Ser. No. 08/285,802, filed on Aug. 4, 1994, and issued as U.S. Pat. No. 5,549,202 which is a continuation of application Ser. No. 07/967,361 filed Jan. 4, 1993, and issued as U.S. Pat. No. 5,360,422, which is a continuation of application Ser. No. 07/533,886, filed Jun. 6, 1990 and issued as U.S. Pat. No. 5,203,348.

BACKGROUND OF THE INVENTION

The present invention relates to field of electrical defibrillation, including cardioversion, and more particularly to the structure for an electrode used in implantable defibrillation systems. The term "defibrillation", as used herein, includes cardioversion which is another technique involving relatively high energy delivery, as compared to pacing, as well as other aspects of defibrillation therapy such as the monitoring of cardiac electrical activity (sensing) when not delivering high energy impulses.

Defibrillation is a technique employed to counter arrhythmic heart conditions including some tachycardias, flutter and fibrillation in the atria and/or ventricles. Typically, electrodes are employed to stimulate the heart with electrical impulses or shocks, of a magnitude substantially greater than pulses used in cardiac pacing. One defibrillation approach involves placing electrically conductive paddle electrodes against the chest of the patient. During cardiac surgery, such paddles can be placed directly against the heart to apply the necessary electrical energy.

More recent defibrillation systems include body implantable electrodes. Such electrodes can be in the form of patches applied directly to epicardial tissue, or at the distal end regions of intravascular catheters, inserted into a selected cardiac chamber. U.S. Pat. No. 4,603,705 (Speicher et al), for example, discloses an intravascular catheter with multiple electrodes, employed either alone or in combination with an epicardial patch electrode. Compliant epicardial defibrillator electrodes are disclosed in U.S. Pat. No. 4,567,900 (Moore).

Epicardial electrodes are considered the most efficient, in the sense that less energy is required for defibrillation as compared to either chest contact paddles or intravascular catheter electrodes. However epicardial electrode implantation is highly invasive, major surgery, since it is necessary to enter the chest cavity, which typically involves spreading of adjacent ribs or splitting of the sternum. This procedure presents a risk of infection. Further, implantation and attachment place physical constraints upon the nature of electrode. These electrodes must be either quite small, or extremely compliant and resistant to fatigue, as they maintain conformal fit to the contracting heart.

Generally, larger defibrillation electrodes are considered more desirable, since they reduce the impedance at or near the electrode. Sensing artifacts also are reduced for larger electrodes. However, larger electrodes are difficult to attach to the epicardium, as they must conform to the heart during the contractions associated with normal cardiac activity. Subcutaneous electrodes are more easily implanted, at less risk to the patient. In a defibrillation electrode or any other implanted device, however, increasing the size generally increases discomfort and surgical risk to the patient.

Increasing the size of a defibrillation electrode affects its electrical performance. Conventional electrodes are subject to "edge effects" arising from the non-uniform distribution of electrical energy when the electrode receives the pulse. In particular, current densities are greater at the edges of the electrode than at interior regions of the electrode. An attempt to counter the edge effect is disclosed in U.S. Pat. No. 4,291,707 (Heilman et al). A series of circular openings, through an insulative layer framing a conductive screen, are said to substantially eliminate the edge effect by the additional exposure of the screen. Another problem encountered in larger electrodes is the resistance across the length (largest linear dimension) of the electrode, leading to unwanted voltage gradients across the electrode which can degrade electrode performance.

Therefore, it is an object of the present invention to provide an implantable defibrillation electrode with a large effective surface area to lower the impedance at or near the electrode, without causing undue patient discomfort.

Another object is to provide a defibrillation electrode that has a large effective area, yet is easier to implant and readily conforms to the contours of its implant location.

A further object is to provide a defibrillation electrode structure enabling a relatively large size while reducing the non-uniform field distribution associated with conventional electrodes.

Yet another object is to provide defibrillation electrodes of sufficient size and effectiveness to enable transthoracic delivery of defibrillation pulses, with an implanted system.

SUMMARY OF THE INVENTION

To achieve these and other objects, there is provided a body implantable tissue stimulating electrode. The electrode includes a plurality of flexible, electrically conductive electrode segments having a nominal width and a length at least five times the nominal width. A means is provided for mechanically coupling the electrode segments with respect to one another whereby each of the segments, over the majority of its length, is spaced apart from each one of the other segments by a distance of at least 1.5 cm. A means is provided for electrically coupling the electrode segments for substantially simultaneous reception of the tissue stimulating electrical pulses from a pulse generating means. Consequently the electrode segments, when receiving the tissue stimulating pulses, cooperate to define an effective electrode area incorporating the electrode segments and having a width of at least 1.5 cm.

In one preferred configuration, the electrode segments are linear and in parallel spaced apart relation, all extending in a longitudinal direction. The mechanical and electrical coupling means can be a transversely extended distal portion of an elongate, electrically conductive lead. The lead is connected to each of the respective first end portions of the electrode segments along its distal region, and connected at its proximal end to a pulse generating means. Preferably an electrically insulative layer covers the lead, leaving the electrode segments exposed, to define a substantially rectangular "phantom" area or effective electrode area.

Alternatively, the electrode segments can radiate outwardly from a common junction, typically at the distal end of the lead or conductive coupling wire from the pulse generating means. While the coupling wire is covered with an insulative material over the majority of its length, a distal end portion of the coupling wire can be left exposed, to provide one of the electrode segments.

Yet another approach involves a single electrically conductive wire or path, with portions of the path providing the spaced apart segments. As an example, the path can be

arranged in a serpentine configuration in which segments are parallel to and aligned with one another, side by side. Alternatively, the conductive path is formed as a spiral. In either event, adjacent segments are spaced apart from one another a distance substantially greater than their width, preferably by an order of magnitude or more.

In a preferred example, elongate electrode segments about 30 cm long and with a nominal width of 0.5 mm extend longitudinally, aligned with one another and spaced apart from one another by about 3 cm. One end of each electrode segment is mounted to the distal end portion of a conductive lead to a pulse generator. At the opposite, free end of each segment is an enlargement such as a loop or flared end, formed to minimize local high current densities due to the previously described edge effects. The combination of a large phantom area with multiple conductive segments reduces non-uniform current distributions.

The best results are achieved with highly conductive electrode segments. Accordingly, the segments are preferably formed of low resistance composite conductors including drawn braised strands (DBS), drawn filled tubes (DFT) and the like, coated with platinum or another metal from the platinum group, e.g. iridium, ruthenium or palladium, or alternatively with an alloy of one of these metals. The strands can be formed of titanium or platinum. A suitable filled tubular conductor is composed of a silver core within a stainless steel tube. The electrode segments can be formed of single wires, pluralities of wires in a braided or twisted configuration, helically wound coils, or a woven mesh or screen. In some embodiments, particularly those employing the woven screen, it is further desirable to include an insulative backing to more positively position the electrode segments with respect to one another.

It has been found that highly conductive electrode segments reduce any voltage gradient across the electrode, with the separate segments simultaneously receiving a defibrillation or other stimulation pulse. The separate segments thus cooperate to act as a single "patch" electrode, having an effective surface area equal to that of a rectangle or other polygon containing all of the segments. As an example, an electrode formed as a row of five parallel electrode segments spaced apart from one another by 3 cm, each segment being 10 cm long, would have a rectangular phantom or effective area slightly larger than 120 (twelve times ten) square cm. Yet, as compared to a continuous rectangular patch electrode measuring ten by twelve cm, the branched segment electrode in accordance with the present invention is easier to implant, reduces the high current density regions, and more easily conforms to the thorax or other surface to which it is attached. In fact, branched arrangements of segments can provide effective defibrillation electrode areas in the range of from 100 to 200 square cm, while enabling easy implantation.

Thus, in accordance with the present invention there is disclosed a process for applying defibrillation pulses to a human heart, including the following steps:

(a) implanting a first compliant electrode in a patient, proximate the pleural cavity and the rib cage, and on a first side of the thoracic region of the body;

(b) implanting a second compliant electrode in the body, proximate the pleural cavity, and the rib cage, and on a second side of the thoracic region opposite the first side, with at least a portion of the heart between the first and second electrodes;

(c) implanting a defibrillation pulse generator; and

(d) electrically coupling the first and second electrodes to a defibrillation pulse generator and providing defibrillation pulses from the pulse generator across the first and second electrodes.

If desired, one or more electrodes implanted proximate the pleural cavity and rib cage can be used in combination with one or more coil electrodes mounted on an intravascular catheter, preferably positioned in the right atrium and the right ventricle of the heart, with the distal end of the catheter near the apex of the right ventricle.

As compared to the entry into the chest cavity normally associated with implanting epicardial electrodes, transthoracic placement of subcutaneous electrodes as outlined above is substantially less invasive, preserves the integrity of the rib cage and the pleural cavity, and reduces risk of infection.

Nonetheless, other implant locations, including direct attachment to epicardial tissue, can be employed in accordance with the present invention, to achieve relatively large effective electrode areas while maintaining patient comfort with substantially more uniform distribution current density.

IN THE DRAWINGS

For a further understanding of the above and other features and advantages, reference is made to the detailed description and to the drawings, in which:

FIG. **1** is a top plan view of a defibrillation electrode constructed in accordance with the present invention;

FIG. **2** is a sectional view taken along the line **2—2** in FIG. **1**;

FIG. **3** is a sectional view taken along the line **3—3** in FIG. **1**;

FIG. **4** is a top plan view of an alternative embodiment electrode constructed in accordance with the present invention;

FIGS. **5–9** illustrate alternative constructions for electrode segments of the electrodes;

FIG. **10** is plan view of another alternative embodiment electrode constructed in accordance with the present invention;

FIGS. **11–13** illustrate further alternative configurations of the electrode of FIG. **9**;

FIG. **14** is a top plan view of another alternative embodiment electrode;

FIGS. **15**, **16** and **17** illustrate a further embodiment electrode;

FIG. **18** is a top plan view of yet another embodiment electrode;

FIG. **19** is a schematic representation of the electrical field between a continuous patch electrode and an electrode having segments, but in which the segments are too close to one another;

FIG. **20** is a schematic representation of the electrical field between two electrodes constructed according to the present invention;

FIG. **21** is a plot of intraelectrode impedance as a function of the spacing between adjacent segments of each of the electrodes, for electrodes with from two to four segments; and

FIGS. **22**, **23** and **24** diagrammatically illustrate alternative implantation approaches for defibrillation systems incorporating electrodes embodying the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings, there is shown in FIG. **1** a defibrillation electrode **16** including three parallel and

spaced apart electrode segments **18**, **20** and **22**. Each of the segments has a length (L in the figure) substantially longer than its width (W), e.g. 30 cm long with a nominal width preferably about 0.5 mm. Generally, the width should be within the range of from 0.25–5 mm. Adjacent segments are spaced apart a distance (D) substantially greater than the nominal width, e.g. 3 cm. This center-to-center spacing should be at least 1.5 cm, and preferably does not exceed 30 cm.

Electrode segments **18**, **20** and **22** are fixed at respective first ends to a distal end portion **24** of an electrically conductive lead **26**. The lead conducts electrical pulses to the electrode segments from a pulse generator (not shown) coupled to the proximal end of the lead. Lead **26** at the distal end structurally supports the longitudinally extended electrode segments in the transversely spaced apart configuration shown.

The electrically conductive portion of lead **26** is surrounded by an electrically insulative cover or sheath **28**, preferably constructed of a body compatible polymer, e.g. a medical grade silicone rubber or polyurethane. As seen in FIG. **2**, the lead includes a composite conductor formed of a core **30** of silver surrounded by a tube **32** of stainless steel. This type of composite conductor is known as drawn field tube (DFT) of MP35N (brandname) alloy available from FWM Research Products of Fort Wayne, Ind. Further, a coating **34** of platinum is applied over the stainless steel, preferably by sputtering or other deposition process. While preferably platinum, coating **34** also can consist of another metal from the platinum group (e.g. iridium, ruthenium and palladium) or an alloy of these metals. Insulative sheath **28** is contiguous with and surrounds the platinum layer.

As seen in FIG. **3**, the construction of electrode segment **22** (and likewise segments **18** and **20**) over substantially all of its length is substantially similar to the construction of the conductive portion of lead **26**. Thus the segments also are highly electrically conductive. Platinum coating **34** provides a further advantage for the segments, which are not covered by the insulative sheath. In particular, the platinum coating when applied by vapor deposition provides a microtexture which substantially increases the reactive surface area of the electrode segments, to reduce near field impedance of the electrode (the term "near field" impedance refers to the voltage losses associated with the electrode due to chemical and field effects). For a further discussion of this feature, reference is made to U.S. Pat. No. 5,074,313, and assigned to the assignee of the present application. The reduced interface impedance increases the ratio of bulk impedance to the total system impedance as measured between the stimulating electrode and the indifferent or signal return electrode. Thus, more of the voltage drop occurs across tissue, where it is useful for causing the desired stimulation, with proportionately less of the voltage drop occurring at the electrodes where it is non-productive. This enables a reduction in overall potential or pulse duration, in either event reducing the required energy for defibrillation.

Given adequate separation between segments **20**, **22** and **24**, the current distribution is made more uniform. To further counter any current density differentials due to edge effects at the ends of segments **20**, **22** and **24**, loops **36**, **38** and **40** are formed at these ends, respectively. Alternatively, the ends can be flared or otherwise enlarged, and remain substantially free of undesirable concentrations of high current. Such enlargements also facilitate implant, as they tend to positionally fix the electrode segments.

Because the electrode segments are electrically common, the electrodes receive and transmit defibrillation pulses simultaneously. The electrode segments are sufficiently near one another to function in concert, providing an effective area or phantom area incorporating the segments, as indicated in broken lines at **42**. In other words, electrode segments **20**, **22** and **24** define a generally rectangular effective area, with substantially greater compliance to contours and movements of body tissue, as compared to a continuous patch electrode. In addition, the spacing between electrodes performs an important electrical function by producing a substantially more uniform current distribution than that of a continuous patch electrode. Patch electrodes are known to have regions of very high current density around their outside edges, and regions of low current density at their centers. By using a segmented electrode, with segments properly spaced apart from one another, much higher currents can be delivered to the central region of the effective or phantom area because current is able to flow between adjacent segments. This results in a more uniform electrical field across the heart.

FIG. **4** illustrates an alternative embodiment defibrillation electrode **44** including five elongate electrode segments **46**, **48**, **50**, **52** and **54**, each with a preferred width and substantially greater preferred length as described in connection with electrode **16**. Each of electrode segments **46–54** is part of a wire mesh pattern **55** and extends longitudinally. Transversely extended end portions **56** and **57** of the pattern couple the segments to a lead **58**. An insulative sheath **62** surrounds lead **58** from electrode **44** to the proximal end of the lead. An electrically insulative backing **64** supports mesh pattern **55**. The mesh pattern is covered by an insulative layer **66**. Slots **68**, **70**, **72** and **74** are formed in backing **64** and layer **66** between adjacent electrode segments.

FIG. **5** illustrates an alternative form of composite conductor known as DBS (drawn braised strand), available from FWM Research Products, Fort Wayne, Ind. As shown, a silver core **73** is surrounded by six stainless steel wires **75**. The structure is heated and drawn to braise all wires together. The results is a solid, continuous composite conductor composed of a silver core and a stainless steel outer shell or tube.

FIG. **6** illustrates an alternative construction for the electrode segments of either electrode **16** or electrode **44**, involving a plurality of composite conductors **76** in a twisted configuration. Each of the conductors can include a silver core within a stainless steel tube coated with platinum as previously described. Alternative composite conductors for single and multiple wire arrangements include platinum or titanium ribbon or wire, clad with platinum. The twisted construction enhances flexibility and resistance to fatigue in the electrode segments. Other alternatives include braided or knitted wires.

FIG. **7** shows another alternative construction for the electrode segments, in the form of a woven mesh or screen **78** on an electrically insulative backing **80**. This type of electrode segment construction is particularly well suited for epicardial positioning, e.g. with electrode **44** in FIG. **4**.

Another alternative segment construction, shown in FIGS. **8** and **9**, involves a flexible, electrically insulative cylindrical core **82** of polyurethane, medical grade silicone rubber, or other suitable body compatible material. Core **82** is surrounded by an electrically conductive coil winding **84**, preferably a wire or composite cable such as illustrated in FIG. **2**. The helically wound coil conductor provides the greatest flexibility and fatigue resistance of any of the arrangements discussed, and for this reason is preferred in the case of direct epicardial attachment, or any other implant

location in which the lead segments are subject to continued or repeated muscular contraction or other abrupt tissue movements. A disadvantage, relative to other embodiments, is that a helical coil electrode segment, as compared to other segments of equal length, involves a substantially longer conductive path with less tensile strength.

All of the alternative constructions provide electrode segments which are highly compliant, first in the sense that they readily adjust to the contours of body tissue at the implant site when they are implanted, and secondly over the long term, in continually conforming to the tissue during muscular contractions and other tissue movement.

FIG. **10** illustrates a further embodiment defibrillation electrode **86** including electrode segments **88**, **90** and **92** formed as branches, radiating or extended outwardly from a common junction and stress relief area **94**. Junction **94** is positioned at the distal tip region of a lead **96** to a pulse generator (not shown), and includes a conductive portion surrounded by an insulative sheath **98**. The conductive region of the lead and the electrode segments can be constructed as previously described.

The stress relief portion of the electrode is electrically insulative and covers portions of the segments, leaving exposed portions of the segments spaced apart from one another and defining an effective or phantom area **100** shown by the broken line. As before, segments **88–92** have a nominal width preferably about 0.5 mm, and are longer than they are wide, for example by at least a factor of five. At the free ends of the segments are respective masses or bodies **102**, **104** and **106**. The bodies are constructed of an electrically conductive, plastically deformable material such as platinum or gold and, as seen in FIG. **10**, include slots **108** slightly wider than the thickness of segments **88–92**. Each body is applied to the free end of its respective electrode segment by inserting the free end within the respective slot and pinching the body to frictionally secure the body to the electrode segment. Bodies **102–106** thus provide enlargements at the free ends of the segments to reduce the chance for high current densities at the free ends, and provide a means of fixation of the free ends.

FIGS. **11–13** schematically illustrate alternative configurations for electrode **86**. More particularly, FIG. **11** illustrates a clamp **110** for electrically and mechanically coupling two intersecting cables **112** and **114**. Cable **112** is part of lead **96**, with a distal portion of the lead providing center segment **90**. Electrode segments **88** and **92** are opposite portions of cable **114**. An extension **116** of electrically insulative sheath **98** covers clamp **110** and portions of cables **112** and **114**, leaving the segments exposed.

In FIG. **12**, segments **88**, **90** and **92** extend radially from a crimping member **118** at the distal end of lead **96**. Alternatively, segment **90** is the distal end of the lead, in which case the remainder of the lead, crimping member **118** and portions of the electrode segments are provided with an insulative covering **119**.

In FIG. **13**, crimping member **118** secures electrode segments **88**, **90** and **92** to the distal section **120** of lead **96**. Insulative sheath **98** leaves distal section **120** exposed, so that it functions as a fourth electrode segment.

FIG. **14** shows a further embodiment defibrillation electrode **122** including a lead **124** having a distal end **126** formed in a curved, serpentine configuration. An insulative sheath **128** covers the lead and leaves the distal region exposed. Further insulation covers curved portions of the electrode at **130**, **132** and **134**, thus to define four parallel segments or length-portions **136**, **138**, **140** and **142** aligned with one another and side by side.

FIGS. **15**, **16** and **17** disclose alternative serpentine electrode configurations including an electrode **144** with a wire mesh or screen **146** on an electrically insulative backing **148**. FIGS. **15** and **16** illustrate a conductive path **150** including parallel electrode segments **152**, **154**, **156** and **158**. The distal end of segment **158** is enlarged at **160** to counteract edge effect current densities.

In FIG. **17**, an electrode **162** includes a serpentine conductive path **164** formed between a pair of generally rectangular electrically insulative layers **166** and **167**. A serpentine opening in layer **166** exposes part of a wire mesh layer **168**. Slits in the patches at **170**, **172** and **174** allow the patch to conform to the site of implant. Selected parts of the conductive path can be covered with insulation if desired, to leave just parallel segments exposed.

FIG. **18** discloses yet another embodiment defibrillation electrode **176** in which a single conductive path **178** at the distal end of a lead **180** is formed into a spiral. The path can be a coated composite cable or a wire mesh or screen as previously described, with a similar nominal width in the radial direction. The pitch of the spiral, i.e. radial spacing (D) between adjacent arcs in the spiral, is preferably about 3 cm. Thus the effective electrode area encompasses the outermost arc of the spiral, as indicated by the broken line at **182**. The spiral includes at least two complete turns or length-portions as shown, with each turn forming an arcuate electrode segment to provide respective radially inward and outward segments **184** and **186**.

Regardless of the particular embodiment, electrodes constructed in accordance with the present invention provide a substantially larger effective or phantom area than previously practical for implantable defibrillation electrodes. One reason for this is the spacing between adjacent electrode segments, resulting in more compliant electrodes, both in the sense of matching contours in body tissue, and "dynamically" in responding to muscular contractions and other sudden or rapid tissue movement, with virtually no risk of fatigue. Another feature permitting the large size is the highly conductive electrode segments and lead distal end or other feature electrically coupling the electrode segments. This ensures an acceptably low voltage gradient across even relatively large electrodes.

As previously noted, a large but segmented electrode structure results in a substantially more uniform current distribution, as compared to conventional continuous patch electrodes. FIG. **19** schematically illustrates electrical current flow, in broken lines, between a continuous patch electrode **187** and an electrode composed of parallel, spaced apart wires or segments **189**. Adjacent segments **189** are quite close to one another, e.g. spaced apart from one anther a distance of about 5 mm. Because of the low impedance between adjacent segments **189**, there is virtually no potential difference between these segments and intervening tissue. Most of the current flow is along the end segments **189**, and very little occurs near the intermediate segments or between segments. Consequently, the electrode formed of segments **189**, much like electrode **187**, exhibits a non-uniform current distribution, with very high current density at the outside edges and low current density along the medial region.

In FIG. **20**, the electrical current flow between two electrodes with respective segments **191** and **193** exhibits a substantially uniform current density across each electrode. Again the current flow is shown in broken lines, and illustrates the importance of sufficient spacing between adjacent electrode segments. More particularly, the seg-

ments of electrodes **191** and **193** are spaced apart from one another a sufficient distance for intervening tissue to provide substantial electrical impedance between adjacent electrode segments. Thus, each of segments **191** and **193**, including the intermediate segments, responds to the opposite one of the electrode pair, permitting current densities, over the central regions of these electrodes, substantially equal to the current densities at their edges.

FIG. **21** shows the relationship between the spacing between coils or adjacent and parallel electrode segments, and impedance, for groups of two, three and four segments as shown at **195**, **197** and **199**, respectively. In all cases the impedance is highest when adjacent segments are closest together. In all cases, increasing the spacing from 1 cm to the preferred 3 cm reduces impedance, and the cases show some further improvement as spacing is increased beyond 3 cm. For any selected spacing, the four segment electrode exhibits the lowest impedance, which is not surprising in view of the fact that larger electrodes generally exhibit lower impedance.

Thus, it has been found that electrode performance is substantially improved, in terms of reduced impedance as well as uniformity of the electrical field, when the spacing between adjacent segments is at least 1.5 cm. The upper limit of spacing is less strict, and subject to physical (size and patient comfort) constraints rather than electrical performance constraints. Within these limits, the optimum spacing depends upon the materials employed and the intended location of implant. Generally, however, a spacing of 3 cm between adjacent electrode segments has been found satisfactory.

FIG. **22** schematically illustrates an implanted defibrillation system including spaced apart electrodes **188** and **190**, for example similar to electrode **16**. The defibrillation system further includes a pulse generator **192**, and leads **194** and **196** connecting the pulse generator to electrodes **188** and **190**, respectively. Both of the electrodes are subcutaneous and outside of the rib cage, in the thoracic region. The electrodes are on opposite sides of the heart **198**. More particularly, electrode **188** is positioned to the left of, and anterior with respect to, the heart. Electrode **190** is posterior with respect to the heart, and to the right of the heart. Such transthoracic application of defibrillation pulses requires electrodes having a large surface area, achieved in accordance with the present invention by the spaced apart electrode segments of each electrode. Pulse generator **192** is also mounted anterior and to the left of heart **198**, below electrode **188**. The pulse generator can incorporate circuitry for sensing cardiac electrical activity, in which case electrodes **188** and **190** are used in sensing such activity as well as delivering defibrillation pulses.

FIG. **23** discloses a defibrillation system in which an electrode **200** constructed in accordance with the present invention is coupled to a defibrillation pulse generator **202** by a lead **204**. Another electrode **206**, also constructed according to the present invention, is applied directly to epicardial tissue. Electrode **200** is positioned inside of rib cage **207**, and can be within the pleural cavity if desired. Stimulation occurs across the heart, with electrode **200** to the left of the heart and electrode **206** at the right ventricle.

FIG. **24** shows a defibrillation electrode system including an electrode **208** positioned anterior of and to the left of the heart **210**, as in FIG. **22**. A second electrode **212** is provided as a coil, near the distal end of an intravascular catheter **214** in the right atrium and terminating at the apex of the right ventricle.

Regardless of the location of implant, electrodes, constructed in accordance with the present invention provide relatively large (in the range of 100–300 square cm) effective areas, yet readily conform to contours and contractions or other movement of body tissue. The narrow electrode segments are provided with end loops or other enlargements to counteract high current densities due to edge effects and to provide fixation. The present lead configurations further allow a subcutaneous implantation outside of the rib cage, with effective defibrillation energy production due to large virtual sizes based on the phantom areas incorporating the electrode segments.

What is claimed is:

1. A body implantable tissue stimulating electrode assembly, including:

an elongate, electrically conductive lead having a proximal end region and a distal end region; and

an electrode including a plurality of compliant, electrically conductive electrode segments, each of said segments having a nominal width and a length exceeding the nominal width, said electrode segments having respective and opposite first and second ends and being coupled to the distal end region of the lead for substantially simultaneous reception of tissue stimulating electrical pulses from a pulse generating means at the proximal end region of the lead, said electrode segments being arranged in spaced apart and side-by-side relation such that each of the electrode segments, over most of its length, is spaced apart from each one of the other electrode segments by a distance of at least 1.5 cm, each of the electrode segments being free of electrically insulative material at and along its periphery substantially over its entire length to provide an exposed reactive surface over substantially the entire length and periphery of the electrode segment, said electrode segments when receiving the tissue stimulating pulses cooperating to define an effective electrode area incorporating all of the electrode segments.

2. The assembly of claim **1** wherein:

said electrode segments are linear and in parallel, spaced apart relation to one another, and the length is at least five times the width.

3. The assembly of claim **2** wherein:

said electrode segments are connected at their respective first ends to the distal region of the lead, and extend in a first direction from the distal end region.

4. The assembly of claim **3** further including:

an electrically insulative layer covering the distal end region of the lead.

5. The assembly of claim **1** wherein:

each of the electrode segments further is uniform in section as taken perpendicular to said length, and free of structural discontinuities along its periphery and substantially over its entire length.

6. The assembly of claim **1** wherein:

each of the electrode segments includes at least one electrical conductor wound in a helical coil.

7. The assembly of claim **6** wherein:

each of the electrode segments further includes a flexible, electrically insulative cylindrical core, with said at least one electrical conductor being wound about cylindrical core.

8. The assembly of claim **1** wherein:

said distal end region includes a common junction, and each of the electrode segments extends radially outwardly of the common junction.

9. The assembly of claim 8 wherein:

a single electrically conductive path forms first and second ones of the electrode segments, and a third one of the segments is joined to the midpoint of the electrically conductive path.

10. The assembly of claim 8 wherein:

the distal end region of the lead forms a first one of the electrode segments, and remaining ones of the electrode segments are coupled to the first electrode segment.

11. The assembly of claim 10 further including:

an electrically insulative layer substantially covering the lead but leaving the distal end region exposed.

* * * * *

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United States Patent [19]

Mehmanesh et al.

[11] **Patent Number: 5,849,033**

[45] **Date of Patent: Dec. 15, 1998**

[54] **TEMPORARY MEDICAL ELECTRICAL LEAD**

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PCT Pub. Date: **Jul. 27, 1995**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 184,712, Jan. 21, 1994, Pat. No. 5,527,358.

[51] **Int. Cl.**[6] **A61N 1/05**

[52] **U.S. Cl.** **607/129**

[58] **Field of Search** 607/115, 129–131

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Primary Examiner—William E. Kamm

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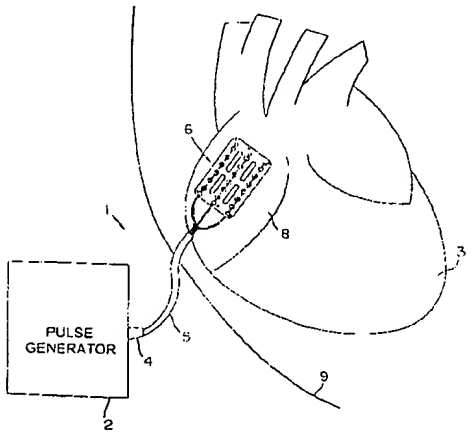
[57] **ABSTRACT**

A temporary atrial defibrillation lead featuring a pad fashioned of a pliant biocompatible material in which three parallel stainless steel defibrillation wire electrodes are mounted. The pad contains holes which expose the electrode wires in a discontinuous fashion. The three electrode wires are merged into one polyurethane insulated lead body, proximal to the pad. At the proximal end of the lead body a stainless steel connector pin with break away needle is mounted, for percutaneous exteriorization of the lead pin, in an area separated from the surgical incision. The break away needle can be broken off to make the connector pin suitable to patient cable connection. The pad is permanently implanted on the atria and remains implanted after removal of the temporary electrode sections. The temporary electrode sections may be removed by gently pulling them at their proximal end. In a preferred embodiment the pad is fashioned of PTFE felt. In an alternate embodiment the pad is fashioned of collagen and is thereby absorbed by the body tissues over time.

13 Claims, 4 Drawing Sheets



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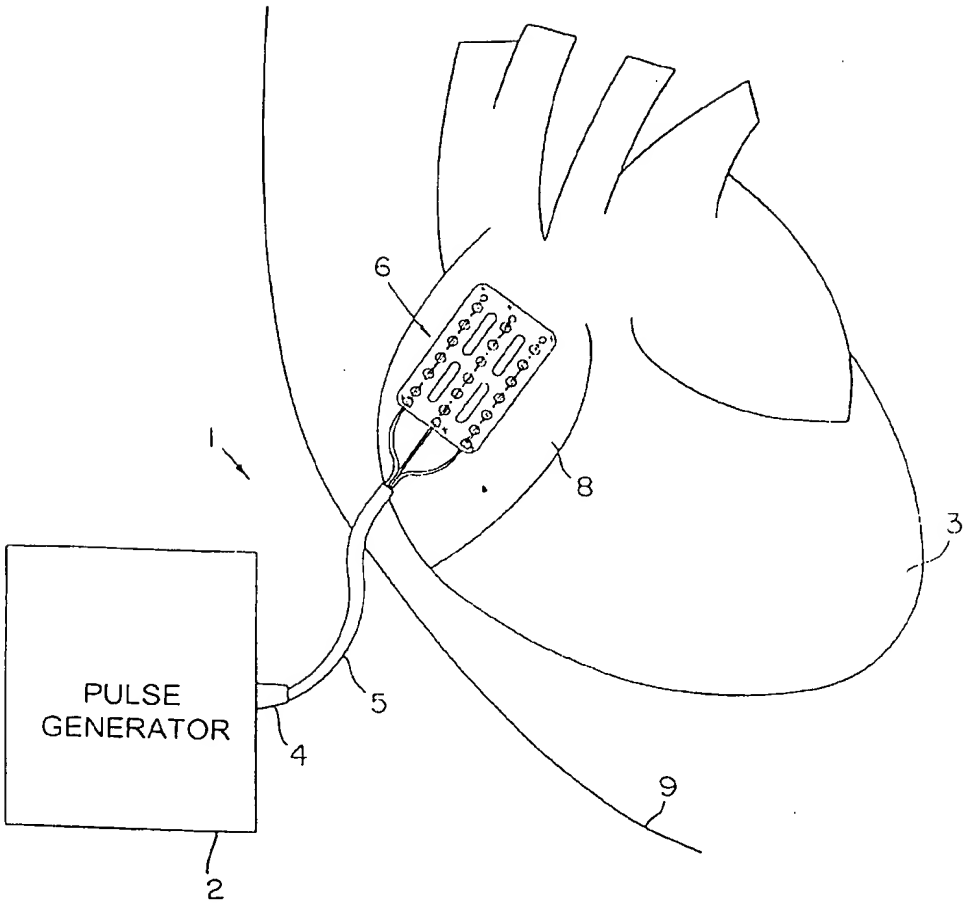

FIG. 1

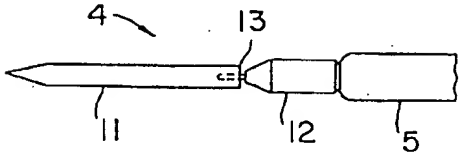

FIG. 2

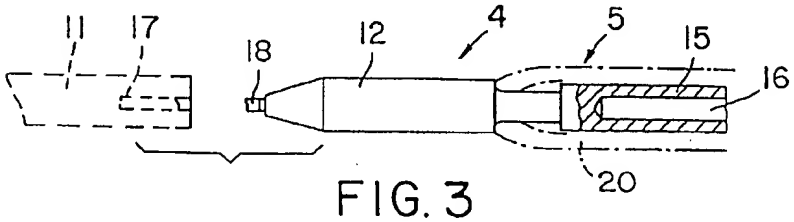

FIG. 3

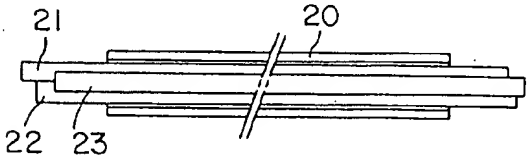

FIG. 4

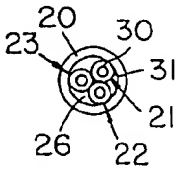

FIG. 5

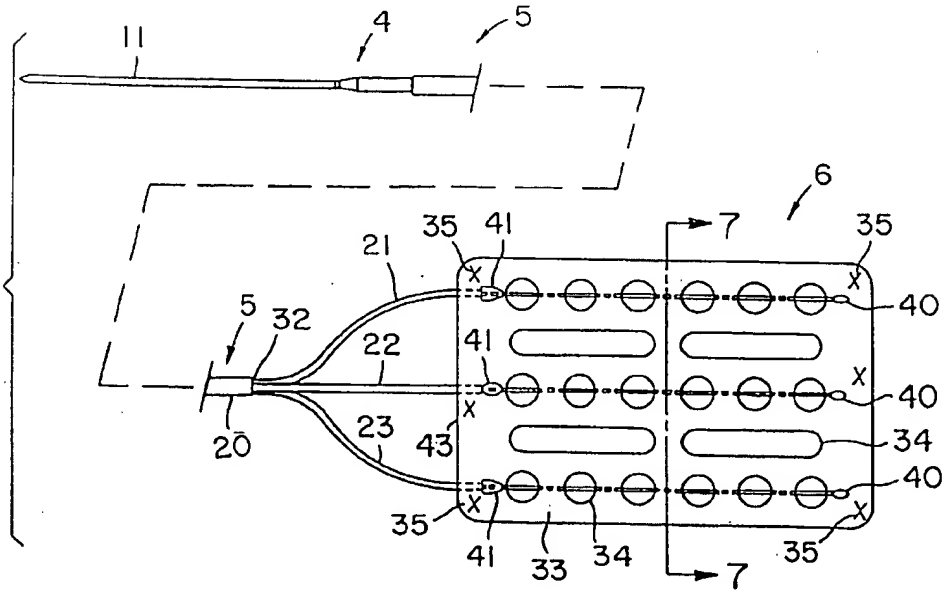

FIG. 6

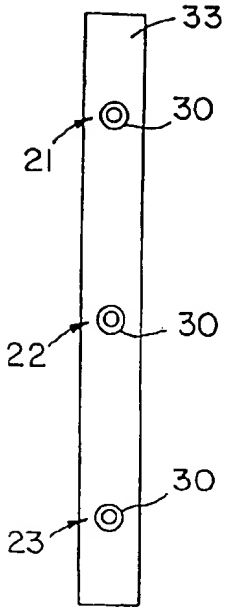

FIG. 7

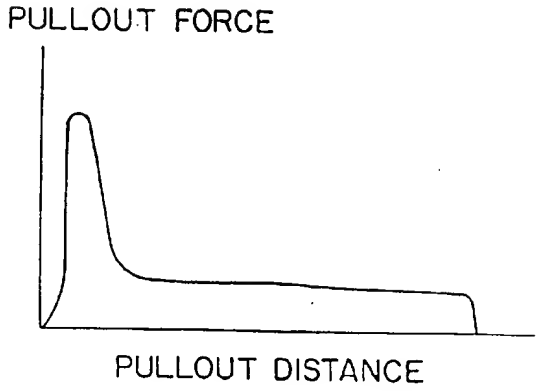

FIG. 9

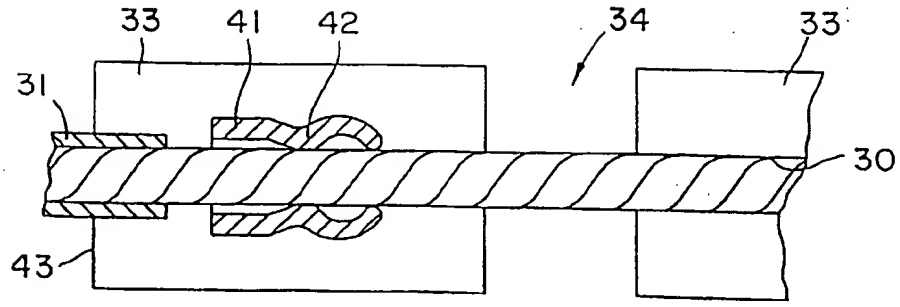

FIG. 8

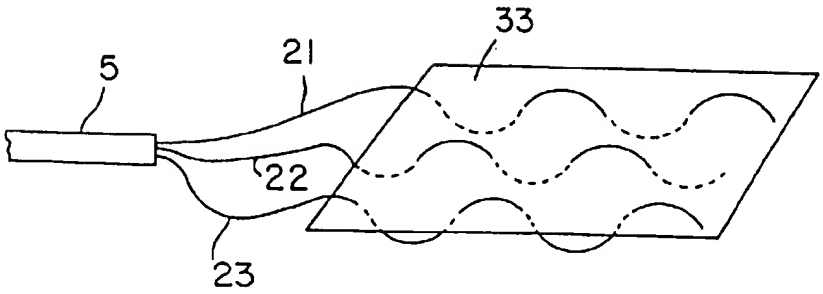

FIG. 10

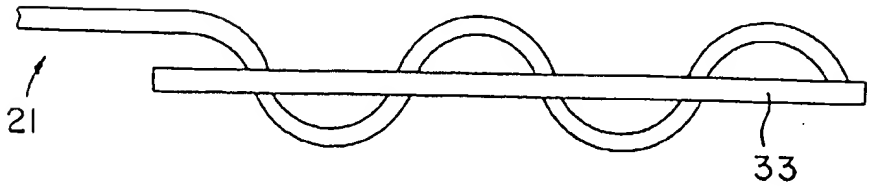

FIG. 11

TEMPORARY MEDICAL ELECTRICAL LEAD

REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of application Ser. No. 08/184,712 now U.S. Pat. No. 5,527,358 entitled "TEMPORARY MEDICAL ELECTRICAL LEAD" of Mehmanesh et al. filed Jan. 21, 1994.

FIELD OF THE INVENTION

The present invention relates to the field of cardiac stimulation and specifically to the field of temporary stimulation of cardiac tissue through a medical electrical lead.

BACKGROUND OF THE INVENTION

Atrial arrhythmias and supra ventricular tachycardias, such as atrial fibrillation, atrial flutter and atrio-ventricular reentries, are a common postoperative complication among patients who have had heart surgery. See, for example, Cardiac Surg. Kirklin J W, Barrat-Boyes B C (Eds.): NY 1993, pg. 210. During the first 10 days after heart surgery it is estimated postoperative supra ventricular tachycardia occurs in up to 63 percent of patients. See, for example, "The Importance of Age as a Predicator of Atrial Fibrillation and Flutter After Coronary Artery Bypass Grafting", Leitch et al., J. Thorac. Cardiovasc. Surg., 1990:100:338–42; "Atrial Activity During Cardioplegia and Postoperative Arrhythmias", Mullen et al., J. Thorac. Cardiovasc. Surg., 1987:94:558–65.

The presence of these arrhythmias, which in an otherwise healthy patient may not be unduly serious, may be especially harmful to heart surgery patients. The hemodynamic condition of these patients is often already compromised by either the surgery itself or the effects of prolonged anaesthesia or both. Supra ventricular tachycardias may further cause a very irregular ventricular rate which may even further deteriorate their hemodynamic condition. Such further deterioration is especially serious for patients with a compromised left ventricular function. These complications may present a serious impediment to the recovery of the patient. See, for example, "Maintenance of Exercise Stroke Volume During Ventricular Versus Atrial Synchronous Pacing: Role of Contractility", Ausubel et al., Circ., 1985:72(5):1037–43; "Basic Physiological Studies on Cardiac Pacing with Special Reference to the Optimal Mode and Rate After Cardiac Surgery", Baller et al., Thorac. Cardiovasc. Surg., 1981:29:168–73.

Due to the serious and potentially life threatening nature of these conditions, postoperative treatment is often aimed at preventing arrhythmias, such as through drugs. Drugs, however, have been found to not always be effective at preventing arrhythmias. Thus it is often necessary to provide a means for terminating any arrhythmias which may occur. One common method used has been through over-pacing.

For example Waldo et al. in "Use of Temporarily Placed Epicardial Atrial Wire Electrodes For The Diagnosis and Treatment of Cardiac Arrhythmias Following Open-Heart Surgery," J. Thorac. Cardiovasc. Surg., 1978, vol. 76, no. 4, pgs. 558–65 discloses the use of a pair of temporary heart wires placed on the atrium to diagnose and treat arrhythmias by antitachy overdrive pacing. Specifically the temporary heart wires were sutured to the atrial wall at the time of the heart surgery. Once the patient was ready to be released the wires were removed by traction or pulling upon their external end.

Temporary postoperative atrial and ventricular pacing with temporary heart wires has been found to successfully treat many of the potential post-operative arrhythmias. As such the procedure has become widespread at least 100,000 procedures per year. Several problems, however, were encountered with the system disclosed by Waldo et al., referred to above. One problem was the stability of the heart wire within the atrial wall. Because the wall undergoes constant motion, the temporary heart wire lead was found to dislodge an unacceptable amount. Secondly, the relatively thin atrial wall, especially on elderly patients, was sometimes torn by traction upon the lead for removal.

An improved method of temporarily affixing heart wires onto the atrium was achieved with the introduction of the Medtronic Model 6500 Temporary Myocardial Pacing Lead System. That lead system featured a silicone atrial fixation disk to fasten the lead to the atrium. Specifically the silicone atrial fixation disk was permanently sutured to the atrium. The lead was positioned so that it was trapped between the disk and the atrial tissue. The lead could thereby be removed by simply pulling it from between the disk and the tissue. The rubber disk remained in the body after removal of the electrodes. The advantages offered by such a fixation system included more reliable lead fixation along with protecting the relatively thin atrial walls from tearing during lead removal. Thus the Medtronic Model 6500 Temporary Myocardial Pacing Lead permitted post-surgical temporary antitachy over-drive pacing to be performed more safely.

In spite of the improved systems or methods to achieve antitachy overdrive pacing it is not, however, always effective in terminating postoperative atrial arrhythmias or supra ventricular tachycardias. When drugs and over-pacing are not effective in the prevention or termination of postoperative supra ventricular tachycardias, or because of main negative inotropic side effects relatively contraindicated, it may become necessary to perform atrial defibrillation, synchronized to the R-wave of the electrogram, to terminate these potentially life-threatening arrythmia. Because of the large energies involved for defibrillation, however, the temporary heart wires could not be used.

External atrial defibrillation, although an effective treatment, has profound side effects. First it should be noted that in contrast to ventricular defibrillation, where conversion to normal sinus rhythm is required at the first shock, atrial defibrillation may be obtained after several shocks because ventricular contraction continues during supra ventricular tachycardia. In addition, due to the high energy required (40 to 360 Joules), the application of shocks, besides their number, is not tolerated well by a conscious patient. Therefore external defibrillation is preferably performed under general anaesthesia or at least sedation. Of course the use of anesthesia gives rise to another risk to the patient.

External defibrillation requires relatively high energy because the electrical source is not positioned directly upon the cardiac tissue but rather must pass through the thorax, which tends to dissipate the energy. In contrast, internally applied atrial defibrillation, such as may occur during surgery through defibrillation paddles placed directly on the heart, requires considerably less energy because the defibrillation electrical energy is applied only to the tissue that needs to be defibrillated. In fact, direct atrial defibrillation may be accomplished with only 1.0 Joule pulses in contrast to the 40 Joule and greater pulses for external defibrillation. See, for example, Kean D., NASPE abs. 246, PACE, April 1992, pt. II, pg. 570.

It should be understood the defibrillation success rate is dependent on the delivered energy. The lower the energy, the

lower the success rate and the higher the number of shocks to be applied to obtain defibrillation success. With direct atrial defibrillation, because the energy may be applied directly to the heart, the energy level can be chosen such that both the shock level as well as the number of shocks required may be tolerated by the patient.

SUMMARY OF THE INVENTION

It is thus an object of the present invention to provide a temporary atrial defibrillation lead which is capable of providing electrical stimulation pulses of sufficient energy to result in defibrillation at a tolerable level.

It is a further object of the invention to provide a temporary atrial defibrillation lead which may provide sufficient energy to the atrium so as to be tolerated by the patient and therefore delivered without the necessity of general anaesthesia.

It is a further object of the invention to provide a temporary atrial defibrillation lead which may be reliably fixed to the atrium through a fixation pad.

It is a further object of the invention to provide a temporary atrial defibrillation lead which may be safely and reliably removed from the atrium.

It is a further object of the invention to provide a temporary atrial defibrillation lead which may be safely and reliably removed from the atrium without the necessity of a surgical intervention.

In accordance with the above objects there is provided a temporary atrial defibrillation lead featuring a PTFE felt pad in which three parallel stainless steel defibrillation wire electrodes are mounted. The pad contains holes which expose the electrode wires in a discontinuous fashion. The three electrode wires are merged into one polyurethane insulated lead body, proximal to the pad. At the proximal end of the lead body a stainless steel connector pin with break away needle are mounted for the percutaneous exteriorization of the lead pin in an area separated from the surgical incision. The break away needle can be broken off to make the connector pin suitable for connection to a therapeutic device, such as a defibrillator. The PTFE pad is permanently implanted on the atria and remains implanted after removal of the temporary electrode sections. The temporary electrode sections may be removed by gently pulling them at their proximal end.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects, advantages and features of the present invention will become apparent from the following specification when taken in conjunction with the accompanying drawings in which like elements are commonly enumerated and in which:

FIG. **1** is a plan view of a lead according to the present invention used to connect a pulse generator to a heart.

FIG. **2** details the connector assembly used in a lead according to the present invention having the break-away needle attached.

FIG. **3** details the connector assembly used in a lead according to the present invention having the break-away needle broken away.

FIGS. **4** and **5** detail the lead body used in a lead according to the present invention.

FIG. **6** is a plan view of a lead according to the present invention.

FIG. **7** is a sectional view of the lead shown in FIG. **6** taken along line **7**—**7**.

FIG. **8** is a sectional detail of the stranded conductor and bus within the mounting pad.

FIG. **9** is a graph illustrating the force required to remove a lead according to the present invention.

FIG. **10** is a perspective view of an alternate embodiment of the present invention.

FIG. **11** is a cross sectional view of the pad of FIG. **10** showing a conductor woven through pad.

The drawings are not necessarily to scale.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** is a plan view of a lead **1** according to the present invention used to connect pulse generator **2** to heart **3**. As seen lead **1** has essentially three sections: connector assembly **4**, lead body **5** and electrode assembly **6**.

Connector assembly **4** connects lead **1** to pulse generator **2**. Details of connector assembly **4** may be seen in FIGS. **2** and **3**. As seen connector assembly **4** features a break-away needle **11** which mates with pin assembly **12**. Specifically break-away needle **11** has recess **17** which mates with finger **18** of pin assembly **12**. In the preferred embodiment pin assembly **12** is stainless steel. Break-away needle **11** is provided on pin assembly **12** to permit the passage of connector assembly **4** from inside the body, through the skin to outside the body. Break-away needle **11** may thereafter be broken off connector assembly **4** at breakpoint **13** to thereby permit pin assembly **12** to join to a pulse generator **2**. As seen in FIG. **3** when break-away needle **11** is broken off it carries with it a portion of finger **18**. Pin assembly **12** further features crimp skirt **15** to permit conductors of lead body **5** to be joined thereto. Specifically conductors are crimped within cavity **16** and thereby electrically connected to pin assembly **4**.

Lead body **5** consists of an insulative outer sleeve **20** encasing a plurality of conductors **21, 22** and **23** as seen in FIGS. **4** and **5**. Gap **26** among inner conductors **21, 22** and **23** is filled by medical adhesive. Outer sleeve **20** may be constructed from any suitable biocompatible material, however in the preferred embodiment outer sleeve **20** is polyurethane.

Inner conductors **21, 22,** and **23** are each constructed in a similar fashion and thus only one need be described. Each is constructed from a stranded conductor **30** encased by inner sleeve **31**. In the preferred embodiment stranded conductor **30** is a multi-filament stainless steel stranded wire and inner sleeve **31** is PTFE or FEP. It should be understood, of course, that any suitable material or wire could be used for conductor **30** including a coiled wire as well as any type of wire made from an acceptable biocompatible metal including, but not limited to, such materials as platinum, palladium, titanium, tantalum, rhodium, iridium, carbon, vitreous carbon and alloys, oxides and nitrides of such metals or other conductive materials. Of course, some materials are incompatible with others and may not be effectively used together. The limitations of specific materials for use with others is well known in the art. It should also be understood that any other suitable material could also be used for inner sleeve **31** such as silicone, polyurethane, PTFE or FEP, for example.

As best seen in FIG. **6** outer sleeve **20** ends at a point **32** away from the distal end of lead **1**. Inner conductors **21, 22,** and **23** extend from point **32** to electrode assembly **6**. Electrode assembly **6** is formed with inner conductors **21, 22, 23** and mounting pad **33**. Specifically distal portion of each inner conductor has each stranded conductor **30**

exposed along the length of mounting pad **33**. Each of the inner conductors **30** is mounted to mounting pad **33**, as best seen in FIGS. **7** and **8**. Although the illustrated preferred embodiment features inner conductors **30** mounted within mounting pad **33**, it should be understood inner conductors may be mounted to mounting pad **33** in any acceptable manner including, without limiting the variations possible, suturing or gluing all or some of inner conductor **30** to an outer surface of the mounting pad **33**. In the preferred embodiment holes **34** within mounting pad **33** are used to provide for intermittent sections of each stranded conductor **30** to be exposed to body tissue. Thus when lead **1**, and specifically electrode assembly **6**, is mounted to cardiac tissue, intermittent sections of each stranded conductor **30** are directly exposed to cardiac tissue through holes **34**. The contour dimensions (length by width of the exposed electrode area) of the conductors is approximately 40 by 30 millimeters in the preferred embodiment. A minimum of two exposed conductors is required to obtain this contour, and by this, a current distribution which results in acceptable defibrillation thresholds (DFT). Application of three conductors is preferred, because it further improves the DFT and the current density at the conductor electrode surface. In the preferred embodiment the conductor electrodes are exposed to both sides of the pad, allowing the current to flow across the front and back side of the pad. This results in a more homogeneous electrical field between the electrodes and usually in a lower DFT.

An alternative embodiment, which yields the same desired characteristics, incorporates a solid pad through which the conductors are threaded or woven, thus being alternatingly exposed to both sides of the pad, as best seen in FIGS. **10** and **11**. Specifically FIG. **10** is a perspective view of a lead shown conductors **21, 22, 23** of lead body **5** woven though pad **33**. FIG. **11** is a cross sectional view of pad **33** of FIG. **10** showing conductor **21** woven through pad **33**. Although as depicted conductors **21, 22,** and **23** are exposed equally to each side of pad **33**, they may also be woven such that a greater length of each is exposed on one side of pad **33** as compared to another side of pad **33**.

Mounting pad **33** further features suture areas **35** (designated by "x"s in the FIGS.) which permit mounting pad **33** to be sutured to the heart, as best seen in FIG. **1**. Mounting pad **33** may be fashioned from any biocompatible pliant, material and in the preferred embodiment mounting pad **33** is fashioned from a PTFE felt. Preferably the structure and porosity of the felt should be similar to those which are typically used in reconstructive heart surgery.

In an alternate embodiment, mounting pad **33** may also be fashioned from a bioabsorbable material such as bovine collagen which has been cross-linked. Cross linking may be accomplished in any acceptable manner, including for example, according to the principles set forth in U.S. Pat. No. 5,264,551 entitled "Process for Cross-Linking Collagen by Diphenyl-phosphorylazide the Cross-Linked Collagen Obtained Thereby and Collagen Based Biomaterials Thus Cross-Linked" issued to Petite et al and assigned to Bioetica of Lyon, France, incorporated herein by reference. The particular degree of cross linking used may depend upon the type of collagen used and the amount of time lead **1** will be used in the body. The degree of cross linking should be such that the mechanical characteristics of pad **33** and the holding force of conductors **21, 22, 23** should be maintained and unintended disengagement of conductors is prevented for a period of at least two weeks to a month. Finally, other types of collagen besides bovine may also be used, such as pig or sheep.

Implantation of lead **1** according to the present invention is as follows. Mounting pad **33** is sutured to atrium **8** using suture areas **35**. Next connector assembly **4** is exteriorized at a point away from the incision through use of break-away needle **11** and pin assembly **12**. Specifically needle **11** is used to pierce the skin from the interior to the exterior so as to expose pin assembly **12**. Once lead **1** is satisfactorily sutured to the atrium, pin assembly **12** is exposed and lead **1** is connected to a pulse generator, the patient's incision may be closed. At this point lead **1** may deliver therapeutic electrical pulses, including defibrillating, cardioverting or pacing, to atrium **8**.

One important aspect of lead **1** of the present invention is its removability. Inner conductors **21, 22, 23** are mounted within mounting pad **33** so they may be removed, even once implanted, by traction. Specifically the inner conductors may be gently removed from mounting pad **33**, and thus body **9**, by traction upon proximal end of lead **1**.

As seen in FIGS. **7** and **8** inner conductors are positioned within mounting pad **33**. Bus **41** (also called a sleeve) is crimped to the conductor. Bus **41** serves to prevent unintended dislodgement of inner conductor **30** out of mounting pad **33**. Bus **41** is placed at the proximal end **43** of pad **33**, at a point between end **43** of pad **33** and hole **34**. As such when inner conductor **30** is removed by traction, bus **41** only needs to pass through a short portion of pad **33** before it is free. Thus only a relatively brief amount of increased force, i.e. a short "jerk" or tug on the distal end of lead body **5** is sufficient to pull bus **41** out of pad **33**. Once bus **41** is outside pad **33** the remainder of inner conductor **30** follows easily as there is no other structure along the length of inner conductor **30** which will inhibit the travel of inner conductor **30** through pad **33**. This is illustrated in FIG. **9** where it is illustrated that pullout distance initially requires a relatively great pullout force, but which rapidly decreases once bus **41** is withdrawn from mounting pad **33**. Thus it may be seen that bus **41** prevents inner conductors **21, 22, 23** from accidentally dislodging from position while also allowing their intended dislodgement and removal without possibly excessive forces from being applied to the atrium **8** during removal. Similar removal properties may be obtained without bus **41**. Application of adhesive (i.e. medical adhesive or polyurethane adhesive) to each conductor or each conductor's insulation and pad **33** creates an adhesive bond between each conductor and pad **33**. Once, by pulling lead body **5**, the adhesive bond is broken, the rest of each conductor may be removed with lower force from pad **33**, which results in a similar removal force characteristic as with bus **41**, discussed below with reference to FIG. **9**. In the preferred embodiment a small amount of medical adhesive **40** (or polyurethane) is applied to the distal end of each conductor **30** in order to cap off the ends of the stranded wire, although other materials, such as polyurethane, may also be used. This is done in order to keep the strands together and to prevent damage to the tissue during the removal procedure or in case the conductor would be forced out of the pad while implanted, as could occur due to heart movement. Mounting pad **33** because it is sutured to the heart, is left in place once conductors and lead body are removed. As discussed above, if mounting pad **33** is fashioned from collagen then if may be absorbed by the body tissues, as is well known in the art. Of course, the time required for absorption depends upon the degree to which the collagen has been cross linked.

Although the invention has been described in detail with particular reference to a preferred embodiment and alternate embodiments thereof, it will be understood variations and

modifications can be effected within the scope of the following claims. Such modifications may include substituting elements or components which perform substantially the same function in substantially the same way to achieve substantially the same result for those described herein.

What is claimed is:

1. A temporary medical electrical lead comprising:

a mounting pad of a pliant biocompatible material; at least one elongate member attached to said mounting pad, said member comprising a conductor and an insulative sleeve, said conductor having a distal region and a proximal region, said insulative sleeve covering said proximal region of said conductor,

characterized in that said distal region of said conductor has means for temporarily affixing the conductor to said pad.

2. A temporary medical electrical lead according to claim 1 wherein said at least one elongate member comprises a plurality of elongate members.

3. A temporary medical electrical lead according to claim 1 wherein said pad (33) has a series of holes (34).

4. A temporary medical electrical lead according to claim 3 wherein said elongate member is mounted within said pad (33) in a position in which it intersects at least one of said holes (34).

5. A temporary medical electrical lead according to claim 1 further comprising said means for temporarily affixing are fastened to said conductor at a point proximal within said distal region.

6. A temporary medical electrical lead according to claim 1 further comprising a plurality of elongate members, said elongate members mounted within said pad (33) in parallel.

7. A temporary medical electrical lead according to claim 1 wherein said pad (33) is porous.

8. A temporary medical electrical lead according to claim 1 wherein said pad (33) is PTFE felt.

9. A temporary medical electrical lead according to claim 1 wherein said pad (33) is collagen.

10. A temporary medical electrical lead according to claim 1 wherein said conductor (21) is a stranded wire.

11. A temporary medical electrical lead according to claim 1 further comprising said proximal end of said elongate conductor is attached to a connector pin assembly.

12. A temporary medical electrical lead according to claim 1 further comprising a needle (11) attached to said connector pin assembly (4).

13. A temporary medical electrical lead according to claim 1 wherein said distal region of said conductor is alternatingly positioned in and out of said pad whereby said conductor is woven through said pad.

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